ATTACHMENT 26

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counterclaimant*.	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **EXPERT REPORT OF DR. T. KIM PARNELL** Complaint Filed: May 10, 2021

Highly Confidential – Subject to Protective Order

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I. QUALIFICATIONS

1. I am a trained Professional Mechanical Engineer (PE) licensed in the State of California. I hold three academic degrees: a B.E.S. in Engineering Science (with Highest Honors) from the Georgia Institute of Technology in 1978, followed by a M.S. and a Ph.D. in Mechanical Engineering from Stanford University in 1979 and 1984, respectively.

2. I am an ASME Fellow and an IEEE Senior Member. ASME is the American Society of Mechanical Engineers and IEEE is the Institute of Electrical & Electronics Engineers. These are the primary professional organizations for Mechanical and Electrical Engineering. There is significant cross-over in terms of combination electro-mechanical devices that need a multi-disciplinary background. I am a Board Member of IEEE-CNSV (Consultants' Network of Silicon Valley). I am also a member of IEEE-EMBS (Engineering in Medicine & Biology), IEEE-CE (Consumer Electronics), IEEE-VTS (Vehicular Technology Society), and IEEE-EPS (Electronics Packaging Society), which focuses specifically on the electronics industry and electronic components, manufacturing, and testing. I have served as an elected officer for several of these groups including as Chair of the IEEE-SCV (Santa Clara Valley) Section (the largest IEEE Section in the world with over 12,000 members in Silicon Valley), Chair of IEEE-CNSV (Consultants' Network of Silicon Valley), and Vice Chair/Treasurer of IEEE-VTS (Vehicular Technology Society). I am also a Member of ASM International (Materials Information Society) and SAE (Society of Automotive Engineers) International. I am Vice-Chair of the NAFEMS Composites Working Group (CWG) which focuses on simulation (Finite Element and other techniques) and on applications of composite materials in all industries.

3. I currently work as an independent consultant through Parnell Engineering & Consulting (PEC). I consult for high-tech industry and legal firms regarding patents, product liability, failure analysis, reliability, and product design/development issues. I have over 30 years

of professional experience using and combining analysis, simulation, inspection, and laboratory measurement to understand and solve engineering problems in a variety of industries and applications. Many of my projects involve products with both electrical and mechanical components and require a multi-disciplinary approach and expertise.

4. I have studied design and ruggedization of a variety of components and systems that must withstand severe service and environmental conditions in service such as medical devices, medical equipment, portable electronic devices, cell phones, and laptops. This experience further includes analyses of materials and material behavior, including elasticity, flexibility, and impact, in addition to deep technical experience with composites, polymeric materials, and manufacturing methods.

5. I have direct experience with manufacturing in multiple industries during my consulting career. This work began in the 1980s and includes various projects up to the present time. These applications include consumer electronics, biomedical, medical device, automotive, petrochemical, paper, metal forming, specialty materials and others. Equipment at issue often involves injection molding, metal forming, stamping, and machining, semiconductor packaging, pipelines and piping components, pressure vessels, sensors and control systems.

6. I began my professional career in 1978 at Bell Laboratories in Indianapolis, Indiana after graduation from Georgia Tech. I was a Member of Technical Staff (MTS) at Bell Labs with a focus on design and development of telephone electro-mechanical components. I worked at Bell Labs before and during my Stanford M.S.M.E. degree, and Bell Labs supported me financially for that degree and I remained on staff.

7. At Bell Laboratories, I worked specifically on keyboard and keypad applications and new design concepts for telephone sets. I built prototypes, studied, tested, and developed

designs utilizing stainless steel domes (caps), silicone rubber domes, piezoelectric polymers, and other novel technologies to simplify design, manufacturing, and assembly in addition to improving reliability. Environmental damage and reduced reliability were of particular concern for telephone sets, especially if the use environment was challenging (dirty, particulates, etc.). The need to develop more reliable and robust keypads and keyboards for these applications motivated this development and the focus on bringing innovative new technologies to the customers in the field. There was a strong emphasis on life-testing at both the component and the system level for all telecom related equipment. Reliability and robust design always represented a central focus throughout Bell Labs and the Bell System. These designs were developed with a keen sense of the importance of the manufacturing and assembly process to the in-service equipment.

8. I took a leave of absence from Bell Labs and returned to Stanford in 1980 to pursue a Ph.D. in Mechanical Engineering and completed that degree in 1984. My work on keyboard and keypad concepts utilizing domes and snap-through buckling behavior for providing a tactile response motivated my Ph.D. research work at Stanford.

9. After Stanford, I then joined SST Systems, Inc. as a Principal Engineer from 1984-1986. In 1986, I joined Failure Analysis Associates, Inc. as a Senior Engineer in the Mechanics and Materials Department. I was promoted to Managing Engineer in 1990. I worked on a wide range of projects as a consultant including aspects such as product failures, product design, and medical device development. The company went public in 1990 as "The Failure Group", but then changed its name to Exponent in the mid-1990's. In 1998, I was promoted to Senior Managing Engineer at Exponent. After 13 years at Exponent, I left to explore the medical device field and joined Rubicor Medical, Inc. in 1999 as Director of Research & Development.

10. When I left Rubicor in 2000, I started offering independent engineering consulting services under Parnell Engineering & Consulting (PEC). I have been an independent consultant from 2000 to the present. During that time, I also worked for MSC Software (2006-2010) in Product Management for finite element simulation software products, consulting, and customer applications.

11. At MSC Software, I was a Senior Manager in the Product Management group, where I contributed in areas such as the User Experience, testing and evaluation of nonlinear simulation tools, and also training. I was recognized as an expert in applications of nonlinear finite element analysis to industry products and challenges. I was an MSC Software technical staff member from 2006-2010 and I consulted with MSC Software extensively from 2000-2018.

12. I was a full-time member of the Mechanical Engineering faculty at Santa Clara University from 2010-2012 and taught classes in Manufacturing, Material Science, Mechanical Design, Finite Element Analysis (FEA), Composite Materials, and Kinematics & Mechanisms. During this time, I served as the Faculty Advisor for several Senior Design Projects. These "real world" Capstone Design Projects encompassed design, system integration, and manufacturing aspects and provided the students with a full product development experience. I also taught graduate courses in Mechanical Engineering at Stanford University from 1995-1996. I have delivered numerous invited presentations, short-courses, and seminars on a range of technical topics to professional organizations and companies. Some of the topics include Mechanical Design for Reliability (MDfR) courses tailored to specific types of products and industries, and Medical Device Technology. I also taught several courses involving the application of simulation and analysis tools and how to better utilize simulation in the design cycle to reduce prototypes, shorten development time, and improve product reliability.

13. My project work includes studies for a broad range of consumer products, equipment, and manufacturing methods. Over the years I have also consulted in the areas of structural mechanics, shock and vibration sensitivity, fracture and fatigue, robust design, and finite element analysis of structures. My practice often encompasses design, failure analysis, forensic investigation, root cause analysis, and reliability issues. My expert work often involves similar issues and often intellectual property matters. Keypad and keyboard concepts include mechanisms, interfaces, and physical design along with volume manufacturing considerations. Recent laptop patent cases involved keyboard technology for moisture resistance, and a laptop display mounting concept to allow the screen to fully pivot or rotate. I also studied enclosures for portable electronic devices for ruggedization and resistance to adverse environments. Hands-on inspection, disassembly, and sometimes destructive evaluations are typical components of projects for portable electronics and medical products.

14. A more comprehensive record of my professional background and technical qualifications is reflected in my curriculum vitae, which is attached hereto as Attachment A. A list of my expert engagements is also included in my curriculum vitae.

15. My opinions and conclusions in this report are based on my years of professional experience in mechanical engineering, failure analysis, and other work in medical devices, medical instruments, consumer electronics, and other sophisticated technology devices. I have relied upon the documents and testimony listed in Attachment B (as well as the materials cited in the text and footnotes of this report). I reserve the right to supplement or amend my report as new information becomes available.

16. I am not currently and have not previously been employed by Surgical Instrument Service Company, Inc. ("SIS"). Counsel for SIS retained me to provide my independent and

objective analysis of several engineering issues in this case, and more specifically to rebut the report submitted by Dr. Robert D. Howe in the SIS action, dated December 2, 2022 ("Howe Report"). Counsel for Larkin Community Hospital, Franciscan Alliance, Inc. and King County Public Hospital District No. 1, d/b/a Valley Medical Center (collectively, "Hospital Plaintiffs") also have retained me to provide my expertise in their case, *In re Da Vinci Surgical Robot Antitrust Litigation*, Lead Case No. 3:21-cv-03825-VC.

II. PRIOR TESTIMONY AND PUBLICATIONS

17. My current *Curriculum Vitae* is attached to this report at Attachment A, and includes a list of prior testimony, and a list of all publications I have authored or co-authored during the past ten years.

III. ENGAGEMENT AND COMPENSATION

18. I am submitting this report at the request of Haley Guiliano LLP, counsel for SIS, the named plaintiff in the lawsuit captioned on this report's first page. This report sets forth opinions I have formed about which I may testify if called as a witness at the trial of this action.

19. I am being compensated for my time spent in this matter at an hourly rate of $600 / hour. If asked to testify in this action, I will be compensated at the rate of $600 / hour for deposition testimony and $600 / hour for testifying at trial. My compensation does not depend in any way on the outcome of this action or the Hospital Plaintiffs' action.

IV. SUMMARY OF OPINIONS

20. Traditional laparoscopic instruments are routinely repaired, and in my opinion, EndoWrists may be similarly repaired. Dr. Howe opines that "there are significant differences between EndoWrist instruments and traditional laparoscopic instruments, and that these differences contribute to EndoWrist instruments having a shorter useful life than traditional

laparoscopic instruments." Howe Report ¶ 13; *see also id.* at ¶¶ 24-33. However, in my opinion, the elements of the EndoWrist identified by Dr. Howe do not preclude repair. Both Si and Xi EndoWrists are based on relatively simple components and engineering principles, and the specific design is now decades old. Actual data and basic engineering principles demonstrate that any differences between EndoWrist instruments and traditional laparoscopic instruments do not justify the use limits imposed by Intuitive's use counter or preclude repair.

21. Dr. Howe opines that "although SIS refers to the 'reset' service Rebotix provides as a 'repair,' Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage." Howe Report ¶ 14; *see also id.* at ¶¶ 33-37. To the contrary, the Rebotix repair process that was initially relied on by SIS is much more comprehensive than just a reset of the use counter and fully addressed the effects of wear and tear on EndoWrist instruments (including those outlined in the Howe Report at ¶¶ 40-43) such that it was proper to repair and return those instruments to hospitals for additional uses. My opinion is based in large part, and as set forth in detail below, on my personal observations of the repair procedure during my visit to Rebotix on August 10, 2021.

22. Dr. Howe contends that (a) the Intuitive EndoWrist use counter "limits 'are determined through a rigorous process involving substantial scientific testing and analysis' to ensure EndoWrist instruments are 'safe, reliable and efficacious'" and (b) "Intuitive's usage limits 'are critical for patient safety, designed in compliance with FDA regulations, requirements and publications, consistent with applicable industry standards as well as EndoWrist labeling and amply supported and validated by scientific testing." Howe Report ¶ 7; *see also id.* at ¶¶ 10, 23,

30, 32, 40-41. To the contrary, the Intuitive use counter has many deficiencies, is not an effective means of preventing instrument failure, and does not ensure proper operation of the EndoWrist. In fact, the use counter fails to account for actual usage or wear and tear (*see* Howe Report ¶ 14), even though Intuitive has the means to do so.

23. Dr. Howe's opinions about "differences" between other medical devices with cables and pulleys that were previously repaired by SIS are unsupported and irrelevant to whether SIS could properly perform an EndoWrist repair pursuant to the EndoWrist repair process I reviewed and observed at Rebotix. Howe Report at ¶ 15; *see also id.* at ¶¶ 38-43. Dr. Howe misunderstands the Rebotix service procedure, does not address detailed underlying documentation, and makes unfounded assertions about potential safety concerns. In my opinion, the Rebotix repair procedure for EndoWrists is thorough and well-documented, and could have easily been utilized by an experienced repair organization such as SIS, as SIS and Rebotix were preparing to do prior to Intuitive shutting down their repair businesses.

24. Dr. Howe's opinions about SIS's reliance on Rebotix processes and Rebotix-supplied information (Howe Report at ¶¶ 16-17; *see also id.* at ¶¶ 44-52) ignore SIS's long-standing relationship with the principals of Rebotix and the respective functions of these companies in the instrument repair industry. Given that SIS and Rebotix were negotiating an agreement for SIS to perform EndoWrist repairs, it would not make sense for Rebotix to provide SIS with the complete underlying confidential testing data and repair procedures prior to reaching a final agreement. Moreover, Rebotix did provide SIS with a comprehensive list of safety protocols and testing that was performed by Rebotix, and in view of the parties' long-standing commercial relationship, it was reasonable for SIS to rely on Rebotix's safety and testing procedures. Indeed, my own review of the underlying Rebotix documentation demonstrates that Rebotix did in fact

sufficiently and reasonably support the safety and reliability of its EndoWrist repair process. In addition, SIS also observed the Rebotix process at both Rebotix's facility and at SIS's own facility. In view of these facts, which Dr. Howe ignored, SIS was justified in relying upon the risk management and testing methods developed by Rebotix.

V. TRADITIONAL LAPAROSCOPIC INSTRUMENTS ARE ROUTINELY REPAIRED - ENDOWRISTS CAN BE SIMILARLY REPAIRED

25. As an initial matter, Dr. Howe selectively misquotes the allegations of SIS's Complaint. For example, he states that "SIS alleges in its Complaint that EndoWrist instruments are 'substantially identical to similar instruments used in traditional surgeries.'" Howe Report ¶ 24. In fact, SIS's Complaint alleges that "**[t]he surgical instruments located at the end of the EndoWrists, such as scalpels, clamps, forceps, scissors, and needle drivers**, are substantially identical to similar instruments used in traditional surgeries."[1] The SIS Complaint then explains that "a wide degree of motion at the working end of the instrument [is] capable of rotation in multiple planes" based on "tungsten cables . . . actuated by internal pulleys of the EndoWrist that mechanically interface with motors within the robot arms of the da Vinci system."[2]

26. Contrary to Dr. Howe's claims, SIS does not ignore that "there are a number of features that are unique to EndoWrist instruments as compared to those in traditional laparoscopic instruments." Howe Report at ¶ 24. Rather, SIS (correctly) alleges that "[t]he materials of the EndoWrist instruments are the same medical grade materials that typically last through hundreds of surgeries and autoclave cycles in other surgical instruments and in medical devices," and that "after completion of SIS's rigorous set of procedures, the EndoWrist instruments are suitable for

[1] SIS Complaint at ¶ 27 (emphasis added).
[2] SIS Complaint at ¶ 29.

many more uses, and at least a number of uses equivalent to Intuitive's originally specified usage limit."[3]

27. I agree with SIS that any purported "features unique to EndoWrist instruments as compared to those in laparoscopic instruments" do not render EndoWrist instruments incapable of repair.

A. Traditional laparoscopic instruments and EndoWrists have many similarities.

28. Both traditional laparoscopic instruments and EndoWrists are designed to be used in minimally invasive surgeries. The distal ends of laparoscopic instruments and the distal ends of EndoWrists are virtually indistinguishable, and each instrument is expected to perform the same function in a surgery. For example, a traditional laparoscopic scissor and an EndoWrist scissor are both designed to cut tissue. They perform essentially the same function:

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MR. ERWIG: Q. Mr. DeSantis, one of the instruments that's described here is scissors; right?
A Yes.
Q And your understanding of the function of scissors in surgery is to cut tissue; right?
A Yes.
Q And the scissors on the end of the EndoWrist, those are designed to cut tissue; right?
A Yes.
Q And the scissors on the end of traditional laparoscopic instruments, those are designed to cut tissue as well; right?
A Yes.
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Q And what it means for something to be similar in terms of intended use is that those two things are performing essentially the same effect in surgery;

[3] SIS Complaint at ¶ 35.

4 right?
5 A Yes.[4]

29. Intuitive's own initial 510(k) submissions and its understanding of EndoWrists confirm the similarities between EndoWrists and traditional laparoscopic instruments. The working ends and elements of the EndoWrists are "essentially identical in size and shape to the predicate devices" – laparoscopic instruments.[5] And the EndoWrists themselves "are essentially identical in terms of shape, size, function, and tissue effect" to the instruments that Intuitive identified as predicate devices in its initial 1999 510(k) submission to the FDA.[6]

B. Traditional laparoscopic instruments are routinely repaired

30. Traditional laparoscopic instruments experience failures as they are used.[7] The scissors at the end of traditional laparoscopic devices become dull and are eventually not sharp enough to cut tissue during surgery.[8] Graspers become misaligned or unable to grasp with sufficient force.[9] And needle drivers loosen such that they cannot hold a needle as tightly as required for precise use during surgery.[10]

31. Hospitals evaluate wear on these instruments by assessing whether they are performing their required function in surgery.[11] Hospitals will assess a traditional instrument both in a pre-operative inspection and during an actual surgery. If an instrument is not performing its function appropriately, hospitals will repair that instrument. It is a standard practice of hospitals to repair instruments used in traditional laparoscopic surgeries.[12] In those repairs, the traditional

[4] DeSantis depo tr., 95:13 – 96:5
[5] Mark Johnson depo tr., 28:12-17.
[6] *Id*. at 31:8-23.
[7] DeSantis depo tr., 134:21-23.
[8] *Id*. at 134:24 – 135:1.
[9] *Id*. at 135:2-5.
[10] *Id*. at 135:6-8.
[11] Harrich, depo tr., 36:5-8.
[12] *See*, e.g., Donovan depo tr., 29:14-18, Harrich depo tr., 32:17-33:3.

instruments are cleaned, aligned and bent into shape, sharpened, and inspected under a microscope.[13] The continued reuse and repair of those instruments allows the hospital to continue to use them for surgeries.[14] And evidence I have reviewed indicates that hospitals will not repair or service a product if that repair or service could make the repaired/serviced product unsafe for use.[15]

32. Bob Overmars, the president of BPI Medical, a company that has repaired "tens of thousands" of laparoscopic instruments, testified that traditional laparoscopic instruments can be used "dozens to hundreds" of times before being sent in for repair.

14 Q. One of the instruments you indicated you
15 repaired is laparoscopic instruments; is that right?
16 A. That's correct.
17 Q. When did you first start repairing
18 laparoscopic instruments?
19 A. Over 20 years ago.
20 Q. What is your best estimate of how many
21 laparoscopic instruments BPI Medical has repaired?
22 A. Tens of thousands
...
4 Q. Is one of the laparoscopic instruments that
5 BPI Medical repairs the Deknatel Snowden-Pencer
6 Diamond-Touch?
7 MR. FOLGER: Objection to form.
8 BY MR. LYON:
9 Q. I didn't hear your response.
10 A. Yes, we do.[16]

33. SIS similarly has decades of experience repairing laparoscopic instruments.[17]

[13] Harrich depo tr., 33:5-12.
[14] *Id*. at 33:5-16.
[15] *Id*. at 26:9-12.
[16] Overmars depo. tr., 96:14-97:10.
[17] Conversations with G. Posdal.

34. Laparoscopic instruments in need of repair can suffer from unintuitive motion, insufficient grip force, dull or damaged scissor blades, and worn or damaged cables. Those failure modes are common in laparoscopic instruments in need of repair. And a hospital makes the determination to send in an instrument based on the wear it has experienced and its inability to perform functions in surgery.

Q. How many times is a typical laparoscopic instrument used before it's sent to you for repairs?
A. It could be dozens to hundreds.
Q. What determines if it's dozens or hundreds?
A. There will be lack of grip of the instrument jaws. There will be dull scissors. There will be broken or failed components.
Q. Are these some of the problems you see in a laparoscopic instrument in need of repair?
A. Absolutely.
Q. Is unintuitive motion one of the problems you commonly see in a laparoscopic instrument in need of repair?
A. Correct.
Q. Is insufficient grip force one of the problems you typically see in a laparoscopic

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instrument in need of repair?
A. Correct.
Q. Is dull or damaged scissor blades one of the problems you typically see in a laparoscopic instrument in need of repair?
A. Correct.
Q. Is worn or damaged cables one of the problems you typically see in a laparoscopic instrument in need of repair?
MR. FOLGER: I'll just object to the form.
BY MR. LYON:
Q. Again, I didn't get your answer. Remember to pause. Could you repeat your answer for me. The court reporter may have got it, but I didn't hear it.

16 A. Correct.
17 Q. Are these the sort of prob -- withdrawn.
18 Do you consider these common problems in
19 laparoscopic instruments that you repair?
20 A. Yes.[18]

35. Mr. Overmars and his company have years of experience with both EndoWrists and traditional instruments. In comparison to traditional instruments, EndoWrists are more robust and well-made.

22 How would you compare how well made
23 EndoWrists are relative to traditional laparoscopic
24 instruments?
25 MR. FOLGER: I'll still object to the form.
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1 A. In our 25 years of experience of repairing
2 endo laparoscopic instruments, the EndoWrist is
3 built like a Hummer and the majority of all other
4 laparoscopic instruments are like Ikea. The
5 Intuitive EndoWrist is much more robust, much more
6 uniquely designed, and just simply a way better,
7 longer lasting instrument than a traditional
8 laparoscopic instrument.[19]

36. Mr. Overmars' testimony that EndoWrists are "more robust" and "longer lasting" as compared to traditional laparoscopic instruments was borne out by my own observations at Rebotix's facility, and my subsequent and independent examination of EndoWrists provided to me by counsel. The construction of the EndoWrist was more durable than the construction of similar laparoscopic instruments. I would expect that EndoWrists could potentially withstand more uses

[18] Overmars depo. tr., 98:10-99:20
[19] Overmars depo. tr., 101:22-102:8

between repairs than traditional laparoscopic instruments. The key requirement is careful inspection and screening for any damage.

C. EndoWrists can be routinely repaired in the same manner as traditional laparoscopic instruments.

37. EndoWrists have similar failure modes as traditional laparoscopic instruments. For example, like with laparoscopic scissors, the scissors on EndoWrists also become dull over time and are eventually unable to cut tissue.[20] And similarly, the graspers on an EndoWrist become misaligned, and the needle drivers are not able to hold a needle as tightly as required for reliable surgical use.[21]

38. Hospitals also inspect EndoWrist instruments prior to surgery to determine whether there are any issues with the EndoWrist. And failure modes on EndoWrists, just like on traditional laparoscopic instruments, are obvious.

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Q. Does your hospital undertake any inspection efforts of an EndoWrist before it's used in a surgery?
A. Absolutely.
Q. What process does your hospital undertake to inspect an EndoWrist from Intuitive before it's used in a surgery?
A. So the inspection process will start in central sterile processing. There is multiple steps on processing and packaging those instrumentations, protecting the tips on them.
Once they're packaged, sent through sterile processing, they come into the room. The scrub tech, when they open the trays, will examine them on the field, make sure that the jaws are open and close, that the -- you know, everything is clean, that there is no dried blood, that the ports are working.

[20] DeSantis depo tr., 213:22-25.
[21] *Id*. at 135:2-8.

25 And then the first assist will do that also.
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1 Q. Are traditional laparoscopic instruments used
2 in nonrobotic surgeries inspected in the same way as
3 the EndoWrists are?
4 A. Yeah, there is a little bit of different
5 process. Some of the robotic instruments are a little
6 bit more complicated with their flushing ports or how
7 they're loaded, but, yes, all of our instruments are
8 inspected.
9 Q. Do the EndoWrists sometimes fail the
10 inspection?
11 A. Yes.[22]

39. The failure modes on EndoWrists that hospitals detect before the use counter has expired include misalignment of graspers, frayed cables, chipped tracks, or dull scissors.

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18 Q. What are some of the ways an EndoWrist might
19 fail before it reaches its maximum number of uses?
20 A. So -- okay. So they -- the teeth might
21 misalign. They'll get shifted so that they don't
22 close completely lined up. They'll get a little bit
23 offset.
24 The -- there is like wires, the bands. They
25 fray, so there may be a frayed wire on them.
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1 They roll on a roller, a track, and that
2 track may get chipped or the wire may come over the
3 top of the roller. It's like a pulley. Or the
4 scissors are dull and so they'll gnaw through the
5 tissue instead of making a clean cut.[23]

40. Each of these failures is addressed through the Rebotix repair procedure that SIS initially had performed by Rebotix, and that it was planning to perform in-house, as described

[22] Harrich depo tr., 40:9 – 41:11
[23] Harrich depo tr., 41:18 – 42:4

below (*i.e.*, the "Rebotix repairs" or "Rebotix procedure"). The Rebotix repairs do not make any of these failures more likely.

D. The "Unique" Elements of the EndoWrist Identified by Dr. Howe Do Not Preclude Repair

41. Dr. Howe discusses several differences between traditional laparoscopic instruments and EndoWrists that, in his opinion, make EndoWrists unsuitable for repair. Howe Report at ¶¶ 25-33.

42. First, Dr. Howe asserts that the motor interface of the EndoWrist produces unique constraints and failure modes.[24] Specifically, Dr. Howe asserts that the pins on input pulleys in the motor interface may slip or shear. He also asserts that bearings that enable low friction motion can fail.

43. Second, Dr. Howe asserts that the cable drives in EndoWrists "are more complex to design," may result in faster failures of the instrument, and are unsuitable for repair.[25] Dr. Howe cites to a general mechanical engineering design textbook for broad guidelines (not specific to the EndoWrist).[26] An excerpt from the quoted text does stress that: "…In view of the fact that the life of the wire rope used over sheaves is only finite, it is extremely important that the *designer specify and insist that periodic inspection, lubrication, and maintenance procedures be carried out during the life of the rope*."[27] (emphasis added). This specific guidance for inspection and maintenance is an important part of the Rebotix EndoWrist repair process, as described later in this report.

[24] Howe Report, ¶ 26.
[25] *Id.* at ¶¶ 28-29.
[26] *Id.* at fn. 31-32.
[27] Richard G. Budynas and J. Keith Nisbett, *Shigley's Mechanical Engineering Design*, Ninth Edition, McGraw-Hill, New York, 2008, Chapter 7, pp. 919-921.

44. Third, Dr. Howe asserts that the cleaning and sterilization cycles that EndoWrists are subjected to are "particularly detrimental to continuing reliable operation" and that "[t]he corrosion that results from reprocessing is well-known to degrade wire rope drives."[28]

45. For each of these differences to make an EndoWrist unsuitable for repair, they would either (1) have to be overlooked or ignored in the repair process, or (2) testing would need to confirm that repairs are not feasible or not possible.

1. The Rebotix repair procedure takes any failures in the motor interface into account.

46. In the Rebotix repair process, each EndoWrist is inspected when it is received for repair. If it is discovered that an EndoWrist has any of the motor interface issues identified by Dr. Howe (pin slipping/shearing or failed bearings), Rebotix will not repair that instrument. For example, pin slipping or shearing results in the instrument being unable to move or difficulty in mounting the EndoWrist to the da Vinci robot. Similarly, failed bearings result in the instrument being unable to adequately move the cables and/or roughness in the motion. Those issues would be detected in either (a) the visual inspection of the components inside the instrument's proximal housing, or (b) in Rebotix's cable tensioning procedure.

47. Further, there is no evidence that suggests that any of these failures are more likely to occur after inspection and repair of an instrument in accordance with the Rebotix process. As part of outgoing instrument evaluation, it is verified that all parts of the motor interface are functioning as expected and that there are no issues that would prevent the instrument from functioning properly.

[28] Howe Report ¶¶ 30-31.

48. Moreover, any issues of this type are regularly encountered and easily addressed in surgery. For example, the consequence of slipping or shearing of pins would be unintuitive motion, or difficulty mounting the EndoWrist to the da Vinci robot. Similarly, the failure of bearings that enable low friction motion would lead to excessive input torque requirements, input response that is rough, and unintuitive motion. Such consequences and failures are easily recognized by surgeons, and surgeons regularly and easily replace instruments when they exhibit unintuitive motion during surgery.[29]

2. The Rebotix repair procedure resolves any issues with the cable drive system.

49. Dr. Howe asserts that the EndoWrist cable drive system makes EndoWrists unsuitable for safe repair. I disagree with this assertion. In fact, the Rebotix repair procedure first identifies any cable issues or damage that would make an instrument unsuitable for repair. During the Rebotix repair process, cables are re-tensioned to ensure that motion of the drive wheel corresponds directly with the appropriate response of the distal tool. As long as an EndoWrist is otherwise suitable for repair, any unintuitive response or other cable issues that might exist before the repair process are carefully eliminated with the cable tensioning step.

50. Under the Rebotix repair process, only EndoWrists that exhibit no signs of cable breakage, damage, or wear are considered for repair. There are three main components in a wire cable rope: a core, strands, and filaments.[30] Filaments are bundled into "strands" around a central "strand core."[31] These strands are then combined together into a larger "wire," which is wound around a core of metal or fiber material. The construction of the cable provides for both flexibility and strength.

[29] Harrich depo tr., 43:20-44:19; Mahal Report ¶¶ 19, 57, 59-60.
[30] Intuitive-00029274.
[31] *Id*.

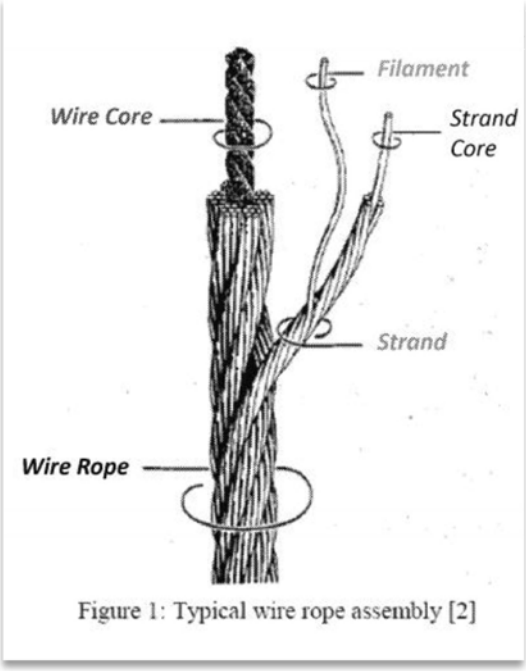


Figure 1: Typical wire rope assembly [2]

Intuitive-00029274

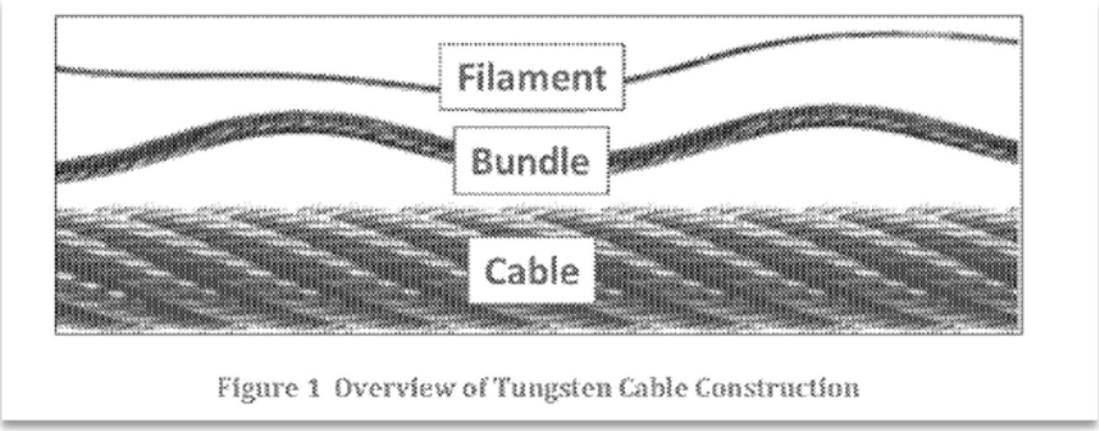
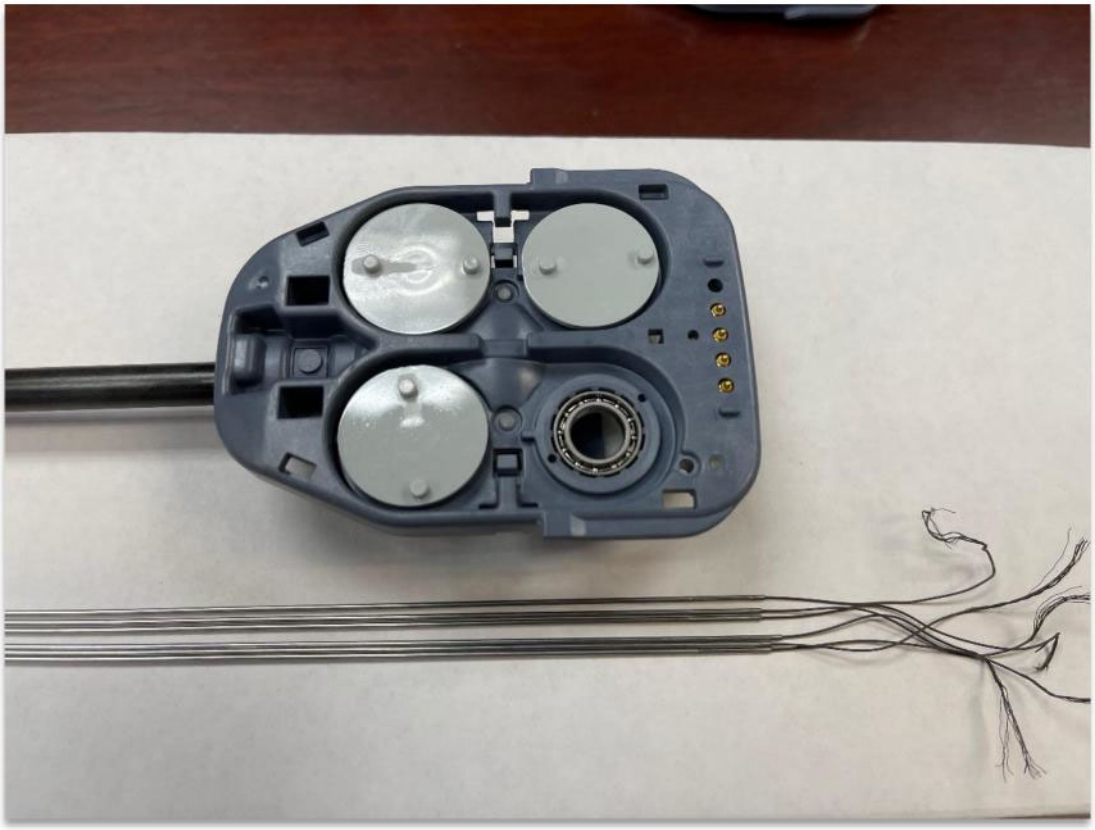


Figure 1 Overview of Tungsten Cable Construction

Another image of the cable construction is pictured in Intuitive's "Risk Benefit Analysis" document for tungsten drive cables. Intuitive-00536538

51. The Intuitive Si EndoWrist designs include cables crimped onto rods at both the proximal and distal ends. The cables freely move at the proximal and distal end around the pulleys, but do not move within the rods. The central rods are inside the full length of the shaft and transmit input motion from the proximal drive to the distal tool.



The cables and the rods onto which those cables are crimped appear on the bottom part of this image (illustration only). Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

52. The Xi design is similar, with the primary difference being cable routing at the proximal end of the instrument due to a 90-degree change in direction between the Xi input discs and shaft compared to the Si EndoWrist.[32]

53. The pulleys and exposed cable at the proximal and distal ends of the instrument are the locations at which the cables could potentially experience wear or damage. During the Rebotix inspection process, the cables are carefully examined at both ends of the EndoWrist (the proximal and the distal end) under a microscope with at least 10x magnification. This process pays particular attention to the areas of cable/pulley contact and interaction. If any fraying or breakage is detected

[32] Duque 30(b)(1) depo. tr., 48:23-52:20; Duque Ex. 241 at Intuitive-00027299.

on even a single wire of the cable, the instrument is not considered a candidate for repair and will not be serviced.[33]

54. This process of careful inspection comports with guidance provided by Intuitive to avoid issues with the cable drive system. For example:[34]

- 2-6: Before use, all instruments should be inspected for damage or irregularities.

55. Finally, the Rebotix procedures address any slack experienced by a cable that would cause unintuitive motion. The Rebotix process evaluates whether the EndoWrist instrument's cable drive system has developed any slack that impedes the proper functioning of the instrument. And each cable is tensioned in the instrument to remove any slack and restore proper tension.

56. Dr. Howe contends that "[c]ables tensioning protocols require test fixtures, torque measurement instruments, and accurate execution of a multi-step protocol" and that this is a "complicated process[.]" Howe Report ¶ 33. The document Dr. Howe cites for this "complicated process" provides a simple two-page procedure,[35] and its manufacturing engineers describe a simple manual or automated process for applying torque to tension the cables.[36] The Rebotix process for tensioning cables is consistent with, and indeed at least as robust as, the processes described by Intuitive documents and engineers.

57. In addition, Intuitive itself concluded that any instrument failures caused by cable failures do not pose risks to patients. When Intuitive analyzed the potential risks associated with unintuitive motion that a cable failure could cause in a document titled "Risk Benefit Analysis: Frayed and Broken Tungsten Drive Cables, Pitch and Grip," it concluded:[37]

[33] Fiegel Conversation.
[34] Intuitive-00536543.
[35] *See* Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012).
[36] Somayaji depo. tr., 80:21-81:16; Duque 30(b)(1) depo. tr., 136:24-146:13.
[37] Intuitive-00536541.

> In any type of surgical procedure, an instrument that loses wristed motion as observed by the surgeon, whether upon insertion or later in the operation, will be immediately replaced with a properly functioning instrument. The immediate and long-range health effects of the use of such an affected instrument would be negligible.

58. Further, Intuitive concluded that cable fragments falling into the patient even in a critical intra-cardiac operation "would be easily retrieved and instrument replaced with only a brief delay in procedure."[38]

59. Intuitive summarized its conclusions about the ease of remedying potential cable-related issues during the medical procedure:[39]

> The user manual provides guidance on the handling of instruments to prevent damage to the cables. However, if damage does occur and fragments or filaments are generated, the visible material can be removed through piece-wise removal or by suction and irrigation. If fragments, filaments, or particulate are not retrieved, the materials meet recognized standards for long term and short term biocompatibility. If the cable damage does not generate fragments, filaments, or particulate in the patient, the instrument can quickly be replaced with a backup instrument, as instructed in the user manual.

60. And ultimately, when assessing the impact of cable fraying or breakage on patients, Intuitive concluded:[40]

> For both grip and pitch cables, the probability of adverse health effects is near zero.

61. Intuitive's conclusions are consistent with surgeons' experiences – these types of failures are easily identified and remedied should they occur during surgeries.[41]

62. Other Intuitive documentation confirms that such cable-related issues are either not a safety issue or "have additional mitigations to limit patient/user risk[.]" "Non-safety related features" are subject to 85%/85% reliability and confidence testing, while safety-related

[38] Intuitive-00536542.
[39] Intuitive-00536544.
[40] Intuitive-00536543.
[41] Mahal Report at ¶¶ 57-61.

requirements "that have additional mitigations to limit patient/user risk" are subject to 90%/90% reliability and confidence testing.[42] Cable-related failures that Intuitive considers to be "non-safety related" include: "Instrument cables . . . derail from pulleys," "Instrument . . . fail[s] in a way that leaves jaws grasping tissue," out-of-spec pitch range of motion, out-of-spec grip range of motion, out-of-spec yaw range of motion, and out-of-spec instrument friction for roll, pitch, yaw, and grip.[43] Cable-related failures that "have additional mitigation to limit patient/user risk" include: "Instrument cables . . . partially or completely break," "Parts or pieces . . . detach from instrument that could fall into patient," and "Instrument [loses] intuitive motion performance during use."[44]

3. Rebotix's repair process addresses any instrument degradation from reprocessing.

63. Although Dr. Howe discusses reprocessing and sterilization generally, he does not cite to any evidence that the minimal number of reprocessing cycles experienced by EndoWrists impact cable drive life or performance in any manner, let alone any manner that would not be discovered or remedied through the Rebotix procedure. Rather, he cites to the U.S. Navy Wire-Rope Handbook for the general proposition that "[c]orrosion accelerates wire-rope deterioration"[45] and also asserts that Intuitive internal documentation states that "[w]hen the number of reprocessing cycles far outnumber the number of uses, early failures can occur."[46]

64. Dr. Howe also cites generally to the "White Paper, Extended Lives Supporting Materials" (Intuitive-00004692) at 4699-700 for the proposition that "[t]he need for these [life testing] precautions is clear from the observed life test failures and RMA returned instrument failures." Howe Report ¶ 32. However, this document does not provide any data to support the

[42] Duque Ex. 268 at Intuitive -02067026; Duque 30(b)(1) depo. tr., 46:5-47:2, 48:9-15, 50:22-51:25.
[43] Duque Ex. 268 at Intuitive -02067029-32 and Intuitive -02067034-37.
[44] Duque Ex. 268 at Intuitive -02067029-32 and Intuitive -02067034-37.
[45] Howe Report ¶ 31 & n. 36l
[46] Howe Report ¶ 30 & n. 35

proposition that corrosion due to reprocessing is a significant cause of failure of EndoWrists. Rather, it states that instruments, "when excessively reprocessed, . . . can fail before they reach their indicated number of uses" without ever defining what would constitute "excessive" reprocessing or discussing any actual failures due to excessive reprocessing.[47] The White Paper notes that FDA guidance requires data to validate reprocessing instructions and acknowledges that it does not have hard data to back up the conclusion that reprocessing impacts instrument lives: "[I]t is *possible* that the implementation of the updated reprocessing guidance has reduced instrument damage during reprocessing . . . ."[48]

65. Without directly tying it to any specific failures, Intuitive does contend that reprocessing can slowly relax the cables in the instrument.[49] For example, Intuitive testing indicates that, for untreated tungsten cables, reprocessing can result in up to a 0.6 µm (or approximately 2.4%) reduction in cable diameter after 200 minutes of exposure to an alkaline solution, while electropolished wire will have a 0.11 µm (or approximately 0.4%) reduction in cable diameter and gold-plated wire will have a 0.04 µm (or approximately 0.15%) reduction in cable diameter under such conditions.[50]

66. While Intuitive certainly has the ability to tighten cables,[51] it has never attempted to repair loose cables on an EndoWrist.[52]

67. As discussed in more detail below, any slack in cables is tightened during the Rebotix repair process. And as further described below, Rebotix has tested its repaired EndoWrists

[47] Intuitive-00004692 at 00004699.
[48] Intuitive-00004692 at 00004670.
[49] McGrogan depo tr., 54:15-25.
[50] Intuitive-00029273 at 00029297.
[51] McGrogan depo tr., 55:9-18.
[52] DeSantis depo tr., 272:15-23; McGrogan depo tr., 55:20-24.

to confirm that they continue to function identically to new EndoWrists. On the other hand, Intuitive has never tested EndoWrists repaired by Rebotix.[53]

VI. THE REBOTIX REPAIR PROCESS IS MUCH MORE THAN A "RESET" AND ADEQUATELY ADDRESSES THE EFFECTS OF WEAR AND TEAR THAT ACCRUE DURING ENDOWRIST USAGE.

68. According to Dr. Howe, "'although SIS refers to the 'reset' service Rebotix provides as a 'repair,' Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage." Howe Report ¶ 14. Dr. Howe then provides a four-paragraph "Overview of Interceptor Technology" without mentioning the steps of the Rebotix process that "address the effects of wear and tear that accrue during EndoWrist usage." I discuss these steps below.

69. In my report below, I discuss the Rebotix repair process that I personally observed at the Rebotix facility. I further discuss the Rebotix repair process and some of the supporting documentation in more detail. I understand that EndoWrist repairs performed for SIS customers, prior to Intuitive shutting down SIS's EndoWrist repair business, were performed by Rebotix.[54]

70. I understand that (a) SIS was in negotiations with Rebotix to perform that repair process at SIS facilities,[55] and (b) in connection with those negotiations, Rebotix did a test run of that process at SIS's facility for a major EndoWrist repair customer, Banner Health.[56]

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[53] DeSantis depo tr., 245:6-11 ("Q. Intuitive has not done testing of any kind to determine whether Rebotix's refurbished EndoWrists can safely be used with the da Vinci robot in surgery; true? A True. We've not done V&V testing, life testing on their instruments, no.")
[54] K. Johnson 30(b)(6) depo tr., 19:5-20:1, 33:22-34-11.
[55] K. Johnson 30(b)(6) depo tr., 33:9-18; Posdal 30(b)(1) depo tr., 28:13-29:24.
[56] Posdal 30(b)(1) depo. tr., 30:5-15.

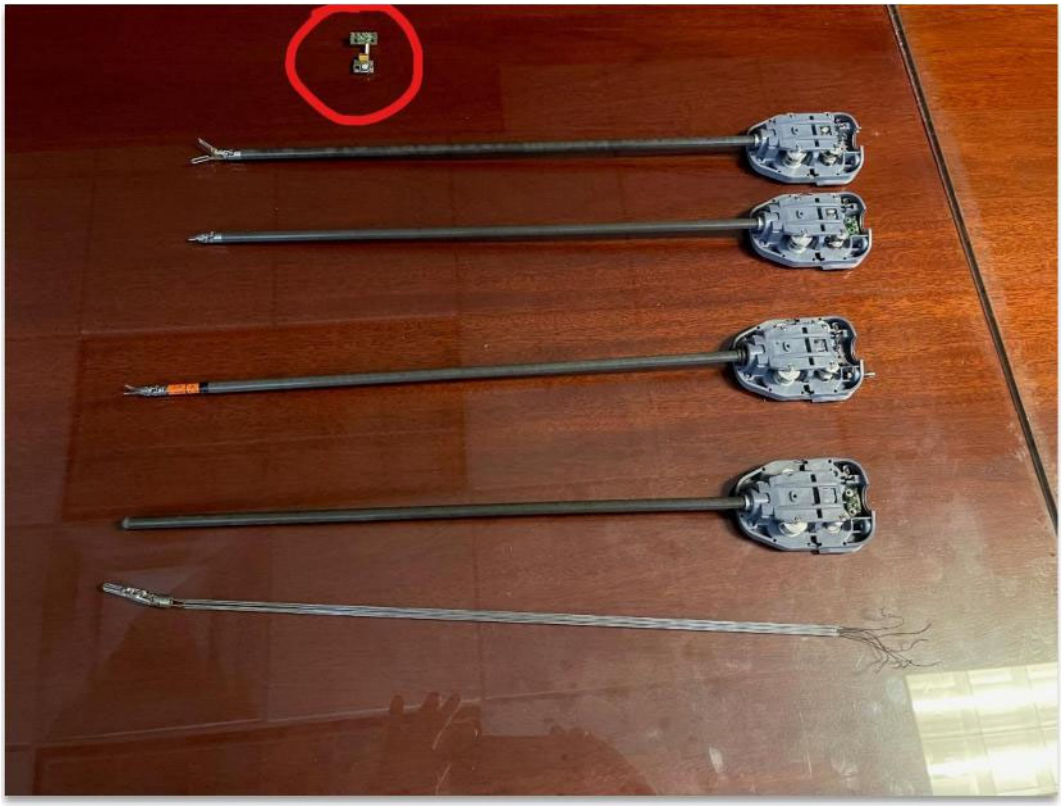
A. Incoming Inspection and Screening

71. When an EndoWrist is received from a customer to be repaired, Rebotix logs that EndoWrist in its inventory. Rebotix then scrubs, flushes, disinfects, and sterilizes that device, as shown in the *EndoWrist Instruments Reprocessing Wall Chart* below.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

72. After this initial process of ultrasonic cleaning and sterilization, Rebotix performs an initial inspection of the device. As part of that inspection, Rebotix removes the housing at the

proximal end of the EndoWrist. A Rebotix technician then performs an initial visual inspection of the entire device to scan for any indication of damage. Rebotix also checks the use counter to determine the number of uses remaining on the device.



This photo shows a selection of the EndoWrists that Rebotix received. The housing on each EndoWrist is removed. The bottom EndoWrist has had the cable system detached for illustration and examination (this is not a standard repair step). Rebotix's Interceptor assembly appears at the top of the image. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

73. After the initial visual check, a Rebotix technician uses an optical microscope at high magnification to examine the tool end of the EndoWrist (the scissors, graspers, etc), the exposed cables, and the pulley system at both the proximal and distal ends of the device. During this step, Rebotix looks for signs of cable fraying, cables misaligned with pulleys, pulley damage, damage to the main tube of the instrument, and any corrosion or contamination on the instrument bearings or the cables.

74. In addition to the visual inspection, when assessing whether the instrument is a candidate for repair, Rebotix operates each drive component through its full range of motion. During this process, Rebotix may determine that a cable has slipped off a pulley and become misaligned or that the device is otherwise unable to operate in its full range of motion.

75. For electrosurgical instruments, Rebotix performs the "Hipot Test" test sequence to ensure that the instruments' insulation and electrical isolation is functioning as required. The test sequence indicates whether there is any damage or breakdown in the electrical insulation and isolation of the device or another issue that prevents the electrosurgical components from functioning safely in terms of their electrical behavior.

This is a photo I took of the Dielectric Withstand Tester that Rebotix uses to run the "Hipot Test" to verify the insulation of electrosurgical EndoWrists. The programmed test sequence results in either a Pass or a Fail result. If the test reads "Fail" instead of "Pass," the instrument is not a candidate for repair. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

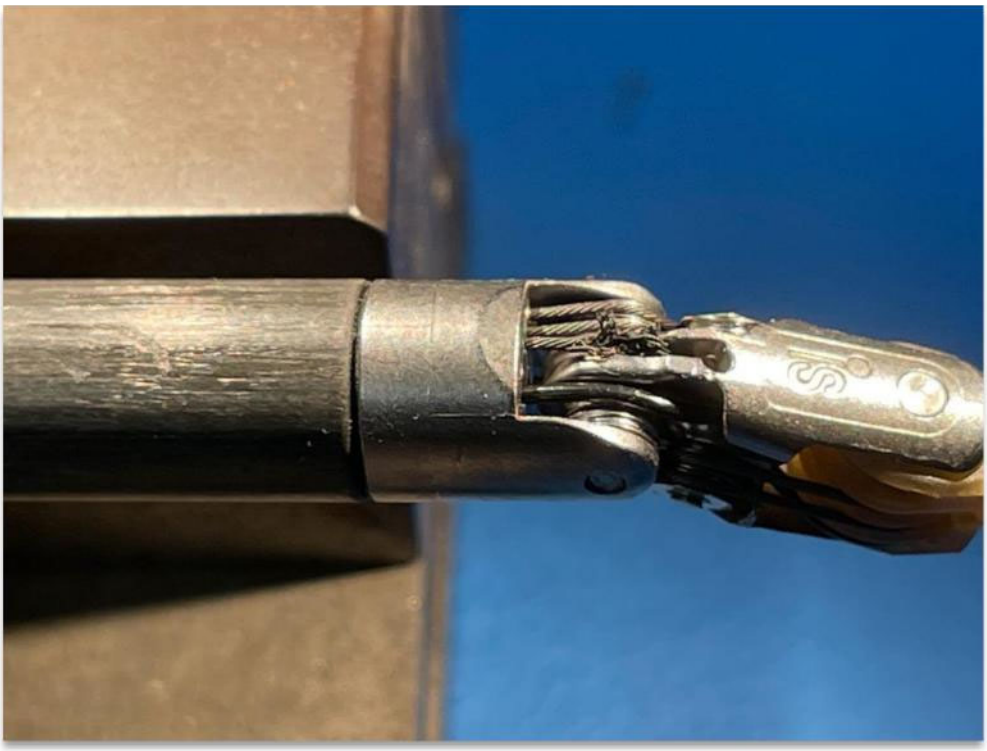
76. These initial inspections are meant to identify whether there is any existing damage to the EndoWrist device that indicates that the specific EndoWrist is "Unsuitable for Repair." Instruments can be "Unsuitable for Repair" due to frayed or broken cables, damage to the pulley

system (including sheared pins or broken bearings), or due to broken instrument tips. Similarly, if there is any damage to an electrosurgical instrument's insulation or the instrument fails the electrosurgical insulation/isolation test, the instrument will not be a candidate for repair.

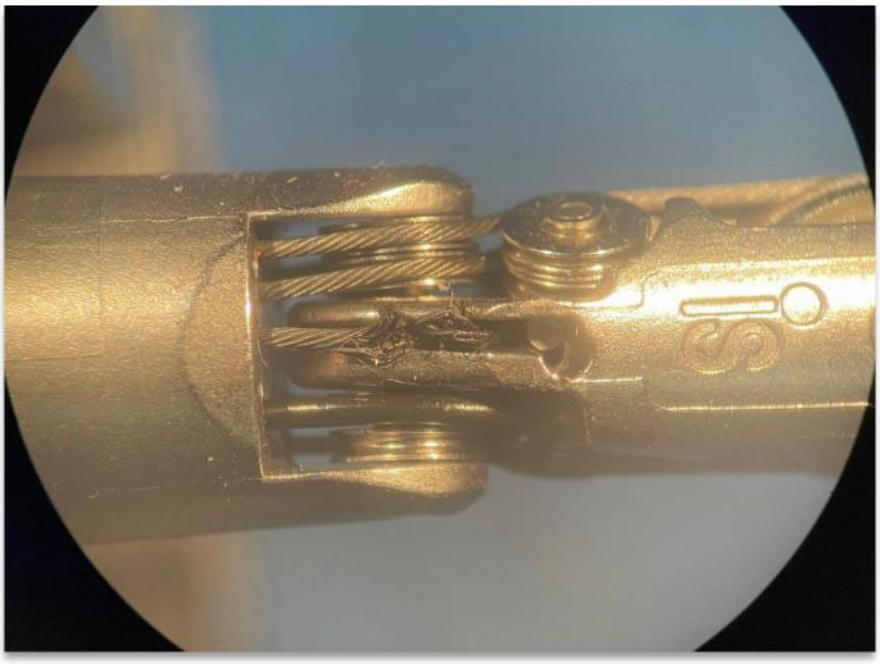
77. When Rebotix determines that an instrument is "Unsuitable for Repair," Rebotix then notifies the hospital that submitted that EndoWrist of that determination. At that point, the device may be returned to the customer or remain in inventory at Rebotix and be labeled as "non-repairable."

78. I inspected several devices at Rebotix that were deemed to be "Unsuitable for Repair." As an example, an EndoWrist with a severed cable was not a repair candidate.

This picture is of an EndoWrist that Rebotix received from a hospital customer that was deemed "Unsuitable for Repair" due to cable damage. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



This is a photo I took of the same EndoWrist. The frayed cable is clearly visible at the distal end of the EndoWrist. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



This is a picture of the same EndoWrist under an optical microscope. The cable tear is clearly visible. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

79. This EndoWrist still had remaining uses on the use counter, indicating that the failure had occurred before the instrument had reached its maximum number of uses. This instrument was received by Rebotix from a hospital that performed a visual inspection prior to surgery.

80. As another example, a PK dissecting forceps with four remaining uses was found to be unsuitable for repair due to a cable break.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

81. In my examination of the EndoWrists that were "Unsuitable for Repair," I did not detect damage due to wear on the instrument. For example, in the cables above, one of the cables in each instrument experienced a break, while the others were fully intact with no signs of fraying. The discrepancy between the cables (one displaying significant damage and the others showing no sign of wear) indicates that one cable was subject to damage from an external object or from

misuse. Other instruments with cables that I examined similarly reflected external damage and breakage, rather than normal wear.

82. This incoming inspection and screening is critical in order to identify EndoWrists with damage that are "Unsuitable for Repair."

B. Interceptor Installation for Use Counter Reset

83. Once an instrument has been identified as a candidate for repair, Rebotix performs a use counter reset by installing the Interceptor component. By doing so, Rebotix restores the use counter to its original value. In other words, if the use counter for an EndoWrist instrument is initially set to ten uses, Rebotix will reset the use counter to the same value of ten uses. By setting the counter back to the same value as the original, Rebotix ensures that the EndoWrists will be sent in for inspection and repair after that limited number of uses. By contrast, traditional laparoscopic instruments do not have a use counter and therefore, are sent in for inspection and repair only when necessary, but not at regular intervals.

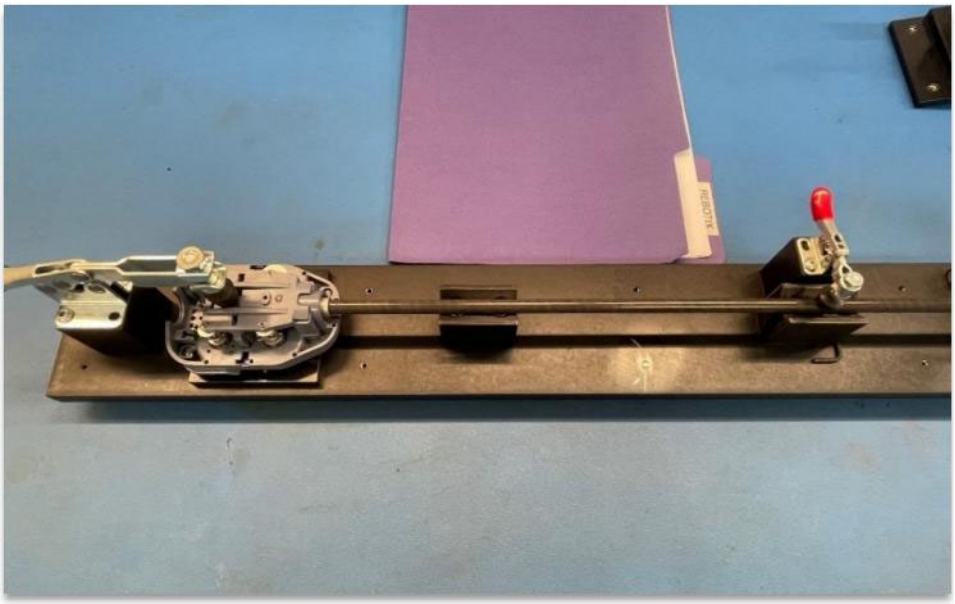
C. Adjustment and Repair

84. After the Interceptor is installed, Rebotix then performs any needed repairs on the tool end of the EndoWrists, such as sharpening scissors, aligning graspers, or ensuring sufficient tightness on needle drivers. Rebotix then makes any needed adjustments to the cables. Rebotix places the EndoWrist in a special fixture and locks the device in its neutral position. This tensioning process involves (a) adjustment of the cable tension, and (b) testing the EndoWrist range of motion and no-load torque for each drive wheel to ensure that the tension is appropriate for surgical use. I personally tensioned the cables on an EndoWrist and was able to readily identify over-tensioning or under-tensioning of the cable. An under-tensioned cable fails to communicate movements precisely to the distal end, while an over-tensioned cable requires excessive additional

torque on the drive wheels at the EndoWrist proximal housing to operate. Indeed, this process is similar to the process utilized by Intuitive for cable tensioning of its Si EndoWrists, while for Xi EndoWrists a similar process is performed using an automated fixture.[57]

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

[57] Duque 30(b)(1) depo. tr., 136:24-146:13.



The Rebotix designed fixture for cable adjustment and tensioning holds the EndoWrist steady in its neutral position and allows for cable tension to be calibrated. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

D. Outgoing Inspection and Evaluation

85. Finally, Rebotix conducts a series of tests on the instrument as part of an outgoing evaluation.[58] As part of that process, Rebotix verifies that the use counter reset was successful and that the instrument shows the original specified number of uses. Rebotix also evaluates whether the instrument's motion is functioning as expected, and whether the tool end of the instrument is performing appropriately (for example, cutting tissue or grasping). In addition, Rebotix performs a second round of testing for electrosurgical EndoWrists in order to verify the integrity of the electrical insulation and isolation of the device.

86. If the EndoWrist passes all of the testing and inspection processes and is deemed fully functional, it is then subjected to another full cleaning process, which includes scrubbing,

[58] REBOTIX123448; REBOTIX134750-REBOTIX134754; REBOTIX134655-134656.

flushing, disinfection, and sterilization. Although EndoWrists are not shipped back to hospitals as sterile, and thus need to be reprocessed upon receipt, this cleaning process ensures that any debris or particulate matter is removed from the EndoWrist.

87. The EndoWrist is then repackaged and returned to the customer. Only an EndoWrist that satisfies both the Rebotix initial quality inspection and the Rebotix final inspection protocol will be returned to the hospital that originally sent that EndoWrist to Rebotix for repair.

E. Repair Process Returns EndoWrists to Original Functional Specifications

88. When Rebotix repairs an EndoWrist instrument, it performs a series of steps that return the EndoWrist to its original functioning specifications. As part of that process, it sharpens scissors, tightens loose cables, and ensures that the instrument performs in a manner equivalent to a new instrument.

89. Rebotix then installs the Interceptor chip, which resets the use counter to its original specification.[59] Rebotix does not increase the use counter to a value beyond the initially specified number of uses. And Rebotix does not otherwise alter the function of the instrument in any way.

90. The equivalent performance between EndoWrists repaired by Rebotix and those sold new by Intuitive has been confirmed by hospitals that have used the Rebotix repair service.

91. When Pullman Regional tested Rebotix-repaired instruments, they determined that "[t]here was no difference than the non-reprocessed instruments," and "didn't have any issues" with the Rebotix-repaired instruments.[60] None of the members of the surgery team at Pullman were able to identify any difference between the Rebotix-repaired EndoWrists and EndoWrists that had not been repaired or serviced by Rebotix.[61] In follow up interviews with the surgical teams that

[59] *See, e.g.,* REBOTIX162185
[60] Harrich depo tr., 37:1-25.
[61] *Id*. at 38:9 – 39:3.

used Rebotix-repaired EndoWrists, Pullman learned "[t]hat the instruments still worked just like the nonrepaired ones. There was no difference."[62]

VII. INADEQUACIES OF THE ENDOWRIST USE COUNTER

92. Dr. Howe asserts that the use counter is an "essential part of the specifications for the EndoWrist instruments" (Howe Report ¶ 23) that ensures that EndoWrists can be used safely. This assertion is false.

93. First, although Dr. Howe contends that the Rebotix repair process does not address "wear and tear" (Howe Report ¶ 14), it is actually Intuitive's use counter that merely measures how many times an instrument has been "used" in a surgery, as opposed to the wear the instrument experiences during the surgery. An instance of "use" itself is poorly correlated with wear, because it does not take into account the time or complexity of the "use" or surgery. Moreso, Intuitive relies merely on the number of "uses," even though it measures and stores data that could easily be used to more accurately measure actual usage, e.g., actual length of time and intensity of the EndoWrist usage during a surgical procedure. As a result, the use counter artificially cuts short the useful life of EndoWrists.

94. Second, although Dr. Howe contends that "[a]n essential part of the specifications for the EndoWrist instruments is a limitation on the number of times each instrument can be used for surgical procedures" (Howe Report ¶ 23), Intuitive's use counter does not take into account the mishandling or misuse of an instrument. An instrument can fail due to mishandling on its first use or on its twentieth.

95. Third, although Dr. Howe contends that "Intuitive's usage limits . . . [are] amply supported and validated by scientific testing" (Howe Report ¶ 7) and that its EndoWrist "designs

[62] *Id*. at 40:2-8.

are life tested" (Howe Report ¶ 32), Intuitive did not adequately perform failure mode testing. Rather, Intuitive's testing on the appropriate number of uses validates a preset target provided by its marketing department, rather than establishing the maximum number of uses an instrument can actually undergo before experiencing a failure.

96. Fourth, although Dr. Howe contends that "Intuitive's usage limits 'are critical for patient safety" (Howe Report ¶ 7), the use counter indicates only that the proximal end of the EndoWrist, which contains the use counter chip, was mounted to the da Vinci robot and entered into "following" mode, thus recording a use and decrementing the use counter. There is no check on the condition of the instrument or an assessment of the instrument's operation; those checks must be performed by the hospital team. The shaft and distal tool end could be totally removed from the instrument and the use counter would still be decremented if the surgeon attempted to operate the instrument. In this sense, the use counter is meaningless as an indicator of the EndoWrist's safe operation.

A. Use counter does not measure actual wear experienced by instruments in surgeries.

1. Surgical procedures vary radically in amount of time and complexity, and therefore result in different amounts of load and stress placed on each instrument used during surgery.

97. All surgeries, including laparoscopic surgeries, range significantly in the amount of time and intensity involved in the procedure. For example, one study highlighted that the "range of operating times is great," and that there is a "relative lack of predictability in procedure times." The study concluded that timing for the most common gynecological laparoscopic procedures ranged between 10 and 400 minutes.[63] There are additional significant ranges in individual

[63] Shushan A, Mohamed H, Magos AL. How long does laparoscopic surgery really take? Lessons learned from 1000 operative laparoscopies. Hum Reprod. 1999 Jan;14(1):39-43. doi: 10.1093/humrep/14.1.39. PMID: 10374091.

procedure times for other types of surgery. For example, surgery for endometriosis might range from 10 to 240 minutes, while a hysterectomy might range between 25 and 400 minutes.[64] And procedure times are generally similar between robotic and non-robotic laparoscopic procedures. For example, one study determined that total operating time "did not differ significantly" between robotic assisted and non-robotic assisted laparoscopic cholecystectomies.[65]

98. Further studies have outlined the significant range in operative time from patient to patient even in the same type of surgeries. One study examining laparoscopic colon surgeries found ranges between 50 and 300 minutes for Ileocecal colectomies, between 62 and 330 minutes for sigmoid colectomies, and between 130 and 590 minutes for total abdominal colectomies.[66] This significant range in the length of surgical time even between patients undergoing the same surgery further illustrates the lack of uniformity in the time that instruments are used during surgery.

99. Instruments used in surgeries can also be used in varying ways. Some instruments might be used for complex anastomosis (sewing or suturing), while other instruments might be used to grasp or hold tissue in a single position during the surgery.[67] Instruments might be used for short periods of intense usage that place great strain on the instrument, or they might be used for long periods with minimal strain placed on the instrument.

100. All of these variables show why there is a variance in frequency of repairs for traditional laparoscopic instruments—they require repair service at different rates depending on how they are used in surgery. As discussed above, Bob Overmars testified that traditional laparoscopic instruments may be used "dozens to hundreds" of times before being repaired, and

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[64] *Id*.
[65] Ruurda, Jelle P., et al. "Analysis of Procedure Time in Robot-Assisted Surgery: Comparative Study in Laparoscopic Cholecystectomy." *Computer Aided Surgery*, vol. 8, no. 1, 2003, pp. 24–29., doi:10.3109/10929080309146099
[66] Scheer, Adena, et al. "Laparoscopic Colon Surgery: Does Operative Time Matter?" *Diseases of the Colon & Rectum*, vol. 52, no. 10, 2009, pp. 1746–1752., doi:10.1007/dcr.0b013e3181b55616.
[67] McGrogan depo tr., 26:8-25.

that the functional characteristics of the instrument, such as "lack of grip of the instrument jaws," and "dull scissors" determines when they require repair.[68] Therefore, an instrument that is heavily used during a few long and intense surgeries will experience more significant wear than an instrument that is used in a much larger number of shorter and less intense surgeries.

101. EndoWrists are similarly used for different amounts of time during surgery—they can be used for a few seconds, a few minutes, or for multiple hours.[69] They are also used in different ways during surgery.[70]

102. A system designed to accurately track the actual wear that an EndoWrist experiences in surgery would consider, at a minimum, both the length of time that instrument has been used, and the complexity of the tasks the instrument performed, in addition to potentially other factors. Intuitive has acknowledged the obvious point that to accurately reflect the wear that an instrument has experienced, one would want to take into account at least the length of time that an instrument was used in surgery and the complexity of the tasks performed in that surgery.[71]

2. <u>The use counter does not account for the length of time or complexity for which an instrument is used during surgery.</u>

103. The use counter decrements a single life as soon as the EndoWrist is manipulated from the surgeon console regardless of the time an instrument has been used or the complexity of the instrument's use during surgery. It follows that the remaining use count does not in any way indicate how or for how long the EndoWrist was used in prior surgeries.

[68] Overmars depo. Tr., 98:10-16.
[69] McGrogan depo. tr., 24:11-17.
[70] *Id*. at 26:8-25.
[71] *Id*. at 32:9-22.

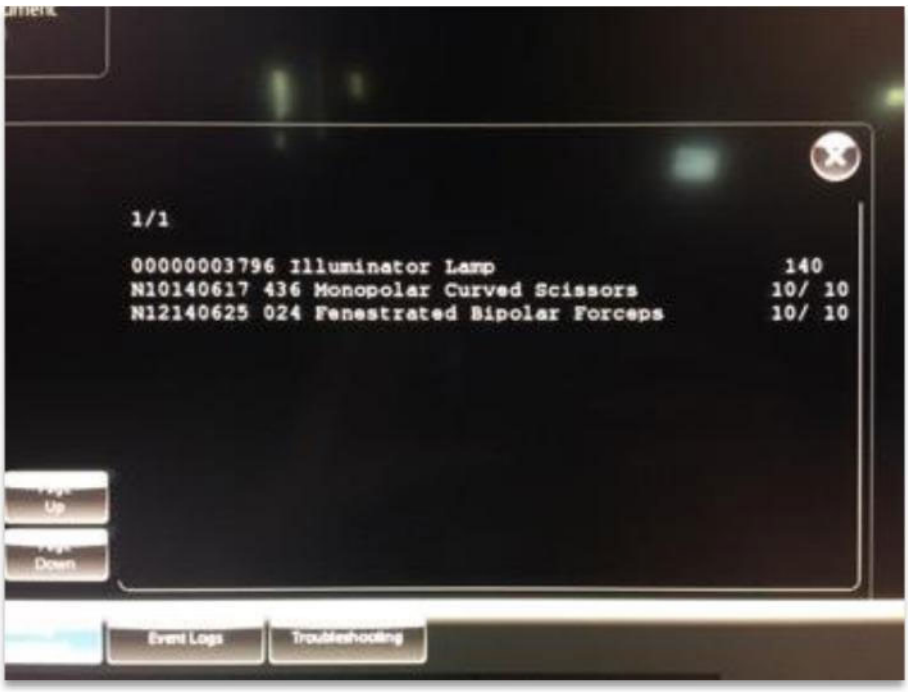


Image from Da Vinci Vision Cart

104. As shown above, the only information that the use counter displays is the serial number, the original number of uses and the remaining number of uses. Once an EndoWrist instrument is attached to the da Vinci robot and used in surgery in any way, a life is subtracted from the use counter.[72] That is the case whether an instrument is used for ten seconds or two hours inside a patient's body.[73]

105. That the dramatic time differences in surgeries discussed in the previous section—ranging between 10 minutes and almost 10 hours—are completely disregarded by Intuitive's use counter is confirmed by Anthony McGrogan, an Intuitive Vice President of product design. At his deposition, McGrogan was asked about two hypothetical EndoWrist instruments: (1) one instrument was used for one minute in each of its ten uses before the use counter read zero and (2) another was used for one hour for each of its ten uses before the use counter read zero. Even though

[72] McGrogan depo tr., 17:13 –18:6.
[73] *Id*.

one instrument was only used for ten minutes in surgery and the other was used for ten hours, Intuitive requires each of those instruments to be thrown away because the use counter in both has been decremented to zero:

Page 24
Q. Now, let's assume that there is one instrument that's used ten times for about an hour
Page 25
per surgery.
Okay? Are you with me?
A. Yep.
Q. That instrument, according to Intuitive, is safe to be used for ten uses; right?
A. Yes.
Q. After those ten uses are up, Intuitive would tell the hospital you need to throw this instrument away; right?
A. Right.
Q. Now, let's take another instrument, same instrument. Let's use a cold grasper. It's used for one minute during surgery at different times.
A. M-hm.
Q. Was that a "yes"?
A. Yes.
Q. Intuitive would also tell the hospital to throw that instrument away after ten uses; right?
A. Yes.
Q. So the first instrument would have been used actually in surgery for ten hours; right?
A. M-hm.
Q. "Yes"?
A. The total surgical time is, I believe, ten -- yes, ten hours.
Page 26
Q. The second instrument would have been used in surgery for ten minutes; right?
A. Yes.
Q. Intuitive would tell hospitals that each one of those instruments needs to be thrown away;

6 right?
7 A. That's true.[74]

106. Further, the complexity of different surgical procedures and the complexity of what each EndoWrist instrument is used for is not reflected in the uses remaining on the use counter. Mr. McGrogan confirmed that hospitals are not required to distinguish between simple and complex procedures.[75] For example, a grasper could be used to grasp tissue a single time during a surgery, or dozens of times. In either case, the use counter will decrement a single life from the instrument, failing altogether to reflect the difference in actual usage between these two instruments.

107. Intuitive's purported inclusion of the use counter is to ensure patient safety, but the use counter itself fails to accurately take into account the key metrics of instrument wear. Measuring the life of an instrument should take into account both the time an instrument has been used and the complexity of the procedures for which the instrument was used—as acknowledged by Mr. McGrogan.

9 Q. Well, one way that Intuitive could measure
10 the life left in an instrument would be to measure
11 the instrument based on the time that it's been used
12 in surgery; right?
13 A. I think we talked that time is not a good
14 metric for measuring wear and tear.
15 Q. Well, the time takes into account how --
16 how long an instrument has been used in a given
17 procedure; right?
18 A. That's all it takes into account.
19 Q. Another thing that you might want to take
20 into account would be the complexity of what the
21 instrument is being used for right?
22 A. That's right.

[74] McGrogan depo. tr., 24:24 – 26:7
[75] McGrogan depo. tr., 28:21-25.

23 MR. RUBY: Object to the form of the
24 question. But it's been answered.
25 ///
Page 33
1 BY MR. ERWIG:
3 Q. I'm sorry. I didn't get your answer.
3 A. I said yes.[76]

Page 33
4 Q. Now, a decrementing of the life on a use
5 counter, that doesn't take into account either the
6 time that the instrument has been used in surgery or
7 the complexity of what the instrument did during the
8 surgery; right?
9 A. That's right, as far as I know.
10 Again, I don't know the details of the
11 algorithm. But, generally speaking, if you use it
12 in surgery, it's going to get decremented.
13 Q. That's the same whether it's been used for
14 ten simple short procedures or ten --
15 A. Yes --
17 Q. -- complex, long procedures; right?
17 A. Yes, yes.[77]

108. Accordingly, the Intuitive use counter does not provide the surgeon with any practical or relevant information about the instrument's actual usage, such as time of use, how the instrument was used, number of particular movements, type of movements, types of procedures, forces experienced, whether an instrument malfunctioned, or whether an instrument was misused or abused.[78] Nor does it account for extreme use cases that might require replacement after a single use.[79]

[76] McGrogan depo. tr., 32:9–33:3.
[77] McGrogan depo. tr., 33:4-17
[78] Mahal Report at ¶ 65.
[79] Mahal Report at ¶ 66.

109. A result of the Intuitive EndoWrist use counter's failure to accurately track an instrument's useful life is that EndoWrists can and do fail prior to the use counter expiring. By the same token, EndoWrists that reach the maximum number of uses may still be capable of safe use beyond that number. This has been borne out in the actual use of EndoWrists--hospitals encounter EndoWrist failures before the use counter has expired, and also have EndoWrists with one remaining use on the use counter that show no signs of wear or failure.[80]

110. Intuitive measures and stores the electrical current of the motors that operate the cable and pulley systems of the EndoWrists during a procedure, which in turn is proportional to the motor torque.[81] Based on this data, Intuitive has the ability to monitor how long an EndoWrist was actually used during surgery as well as the types of forces and movements that the EndoWrist experienced during each surgery.[82] In fact, Intuitive uses this data to identify root causes for EndoWrist failures.[83] Nonetheless, despite having data available that could be used to more accurately determine wear and tear, Intuitive chooses to ignore this information in favor of its simplistic and arbitrary use counter.[84]

111. Traditional laparoscopic instruments do not have use counters.[85] Instead, the instruments are routinely inspected, repaired, and continue to be used.[86] And if an instrument cannot be repaired, that instrument is discarded and no longer used in surgeries.

[80] Harrich depo. tr., 41:12-17. Harrich depo. tr., 59:10-24, Harrich depo. tr., 165 12:20, Donovan depo. tr., 34:20-25, Donovan depo tr., 145:21-146:6.
[81] Duque 30(b)(6) depo. tr., 14:11-15:11.
[82] Duque 30(b)(6) depo. tr., 17:22-18:6.
[83] Duque 30(b)(6) depo. tr., 17:6-18:14.
[84] Duque 30(b)(6) depo. tr., 19:25-20:10.
[85] Mahal Report at ¶ 64.
[86] Donovan depo. tr., 40:9-13, Harrich depo. tr., 45:10-20.

112. Hospitals measure wear on instruments by assessing whether they are performing the required function in surgery. Evidence in these litigations shows that EndoWrists frequently performed no differently by the end of their tenth use than they had on their first use. For example:

Q. You stated that you believed EndoWrists had additional lives on them before you had to dispose of them when they reached their maximum use restrictions; is that right?
A. That's correct.
Q. Why did you believe that EndoWrists had additional lives on them?
A. Well, on the end of the tenth life, it wasn't working any different than it had been on the first life. There was no complaints by the physicians. If there were any, we'd take the instrument out of service or send it back in to Intuitive for repair if it still had lives left on it.
So if it's a grasper, it's a grasper. Is it grabbing the tissue like you think it should? As the physician says, it's feeling that tactile touch. You can't actually feel the touch, but on a console.

Page 36

But it's grabbing the tissue. They're liking what they're seeing. They're liking what they're feeling. So the instrument can still continue to be used.
Q. Is that how you determine whether a traditional laparoscopic device should continue to be used as well?
A. Yes, the functionality of it.[87]

This serves as further evidence of how Intuitive's use counter fails to measure actual instrument wear.

[87] Harrich depo. tr., 35:9 – 36:8

B. The use counter does not take into account mishandling or misuse.

113. Misuse, mishandling, or improper cleaning can occur at any time, including before an instrument's use counter reaches zero. For example, during my visit to the Rebotix facility, I saw numerous instruments that had experienced a failure prior to their use counter expiring. Those failures included snapped tool ends, fully cut cables, frayed wires, and broken instrument shafts.

114. The EndoWrist use counter does not take these failures into account or track whether those failures have occurred.[88] An instrument can have five or six remaining uses, but misuse can cause broken scissors, bent graspers, or broken cables. The only way to accurately determine whether an instrument has been misused or mishandled is through visual inspection and testing. The use counter does not in any way ensure that an instrument has not been subject to mishandling or misuse.

C. Intuitive's life testing is designed to validate an arbitrarily set use limit set by marketing, rather than to establish the failure point of an instrument.

1. To accurately establish a use limit or failure point, tests would need to actually test instruments to failure.

115. In my experience, studying the failures experienced by mechanical components and medical instruments, testing instruments to failure and observing at which points those failures occur, all help to establish the potential range of life for an instrument. Establishing and identifying the potential failure modes accurately is important.[89]

116. As an example, in a sample of ten tested instruments, testing each to failure would involve setting certain failure conditions (such as breaks in instrument cables or dulled scissors)

[88] Mahal Report at ¶¶ 65-66.
[89] *See, e.g.,* "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik.html., and "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/.

and observing at which point each of the instruments experiences a failure. In that ten-instrument sample, one instrument might fail at use 50, and nine others might fail after use 200.

117. By contrast, halting tests after a certain number of uses produces skewed results. In the above example, if testing for the nine other instruments were arbitrarily halted at use 60, the results of the testing would indicate that the instruments had a lower acceptable life. Testing to failure produces an accurate statistical analysis of instrument failures because it actually establishes the range of failure conditions and the useful life of an instrument.

2. Intuitive's testing is designed to validate target lives set by marketing and does not accurately assess the instrument's failure point.

118. Intuitive's life testing does not accurately assess the useful life of an instrument. Instead of attempting to establish the maximum number of lives that an instrument can be safely used, Intuitive's testing aims to statistically validate a preset target limit.

119. The initial targets for an instrument's use counter are set by marketing.

Page 35
9 Q. Now, when Intuitive is first considering
10 what it's going to be setting the lives at,
11 marketing is involved in that process; right?
12 A. Marketing is involved to the extent that
13 they set goals for engineering.
14 Q. For example, marketing might set a goal of
15 ten lives for an instrument; right?
16 A. That's an example, yes.
17 Q. And then engineering would try to design an
18 instrument that would meet that ten-life goal;
18 right?
19 A. Yes.[90]

Q. But when a new instrument is being
6 developed for a customer, marketing is setting the
7 target for that instrument before there's any

[90] McGrogan depo. tr., 35:9-20

8 testing that's conducted; right?...
14 THE WITNESS: Marketing sets a goal for
15 reposable instruments.
16 BY MR. ERWIG:
17 Q. Then engineering designs and tests an
18 instrument to try to achieve that goal; right?
19 A. That's right.[91]

And the testing performed on an instrument to establish the number of lives on the use counter takes place only after those initial targets have been set by marketing and provided to engineering.

19 Q. Now, for formal life testing, formal life
20 testing is performed after there's been a particular
21 target set by marketing; right?
22 A. Typically, yes, formal life testing.
23 Q. That's ultimately what's used when
24 Intuitive sets the life counter; right?
25 A. Yes.[92]

120. Intuitive's Weibull Design of Reliability aims to test a sample of instruments to confirm that instruments will reliably meet a pre-set life target.[93] Intuitive deliberately chooses to stop its life testing protocols shortly after the instruments being tested pass the target number of lives. For example, during Intuitive's life testing for extended life instruments, it prematurely halted testing instead of testing all instruments to failure.[94] For Intuitive's initial life testing of many of its highest-usage Xi EndoWrists, it stopped testing once it justified 10 uses even though none of the instruments experienced a failure.[95]

[91] McGrogan depo. tr., 64:5-19 (objection omitted)
[92] McGrogan depo. Tr., 65:19-25
[93] *See, e.g.,* Intuitive-00542459 – Intuitive-00542461.
[94] Intuitive-00642553.
[95] Duque 30(b)(6) depo. tr., 63:11-64:18; Duque 30(b)(1) depo tr., 115:19-117:15; Duque Ex. 268 (Intutiive-02066979) at 02067029 (stopping testing at 13 life cycles with no failures), 02067033 (stopping testing at 15 life cycles with no failures), 02067034 (stopping testing at 15 life cycles with no failures), 02067038 (stopping testing at 13 life cycles with no failures), 02067039 (stopping testing at 10 life cycles with no failures).

121. The result of this target-based testing approach is that engineers test with those targets in mind and aim to establish reliability for those particular targets. Rather than establishing where failures naturally occur by testing each instrument to failure, the testing process is stopped after justifying the target number of instrument lives.

Page 47
Q. Now, telling the lab to stop testing instruments at a certain point, that could involve telling the lab to stop testing instruments once they've reached 17 uses, for example; right?
A. Yes.
Q. Another option would be not to set any stop point for the instruments; right?
A. Yes.
Q. In other words, continuing to test the instruments until they exhibit failure conditions; right?
A. Yes.
Q. In this particular testing, the instruments were stopped at a certain point; right?
A. Yes.
Q. The testing was not performed all the way through to failure; right?
A. Yes.[96]

Page 45
Q. Sure. Marketing might set a target for 15 lives; right?
A. Sure. Yes.
Q. If instruments were tested to failure, then
Page 46
each instrument would be tested until it experienced a failure condition; right?
A. Yes.
Q. And that could happen at 20 uses; right?
A. Yes.
Q. It could happen at 25 uses?

[96] McGrogan depo. tr., 47:3-20

7 A. Yes.
8 Q. It could happen maybe even at 30 uses?
9 A. Yes.[97]

122. Instruments have passed Intuitive's life testing metrics for higher lives than were actually implemented.

Page 59
9 Q. Well, there's certainly been instances
10 where the instrument being tested passed more lives
11 than were actually implemented; right?
12 A. Yes.
13 Q. Now, the instrument could have been set at
14 a higher number of lives; right?
15 A. Yes.
16 MR. RUBY: Object to the form of the
17 question. The witness has answered.[98]

Page 62
10 Q. There's certainly some instances where the
11 number of lives implemented is different from the
12 number of lives proven; right?
13 A. Yes.
14 Q. And the number of lives implemented, those
15 are less than the lives proven; right?
16 A. Yes, in some cases.[99]

123. Those higher life counts were not implemented because marketing's decision to set the use counter to particular values is driven by maximizing Intuitive's revenue and profits. As early as 1995, in Intuitive's original business plan, it expected to use instruments as a "major part of [its] recurring revenue."[100] Its early 10-K's similarly indicated its intention to extract per-

[97] McGrogan depo. tr., 45:22 – 46:9
[98] McGrogan depo. tr., 59:9-17
[99] McGrogan depo. tr., 62:10-16
[100] Intuitive-00595682.

procedure pricing.[101] And Intuitive's representatives confirmed that use counters with lower life counts would generate more revenue for Intuitive.

Page 143
Q Well, let's assume the same price. If you sell an instrument to a customer that has one use, the customer needs to buy more of those instruments than if an instrument has, let's say, five uses; right?
A Yes. And if you set the same price for the one use and five use, then you would see more revenue, maybe not profit, but on one -- one instrument -- on a one-use instrument.
Q And if the customer only had the option of buying that one-use instrument, it would be better from a revenue perspective to only design a one-use instrument instead of a five-use instrument; right?
A Assuming constant demand and constant volume, from a purely revenue standpoint, not profit, then I think that's a true statement.[102]

124. Intuitive's decision not to re-evaluate the use counter on its Si instruments is a further example of revenue concerns, rather than safety, driving the number of uses that the use counter is set to.

Page 173
Q Now, in 2013, if Intuitive wanted to give hospitals the maximum possible number of uses out of every Si instrument, Intuitive could have tested the Si instruments and seen what the appropriate number of uses was as of that time; right?
A That's -- that's one option, yes.
Q Instead Intuitive left the life counter for the Si instruments at ten uses; right?

[101] *See* 2001 Intuitive 10-K at p. 6 ("In addition, the chip will not allow the instrument to be used for more than the prescribed number of procedures or hours so that its performance meets specifications during each procedure. In addition, we can sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis."). It is telling that even though Intuitive acknowledged the ability to measure time of usage in 2001, it chose the least accurate method of per-use pricing.
[102] DeSantis depo. tr., 143:6-20

10 A Intuitive was investing heavily in a better
11 platform at that time, so we did not choose to invest
12 in the Si instruments to do a life testing and roll
13 out that program. Correct, we did not do that.
14 Q And so Intuitive left the life counter of the
15 Si instruments at ten uses and didn't try to increase
16 it to 12, 13, or anything else; right?
17 A Correct.[103]

125. Intuitive never attempted to extend the lives of Si EndoWrists, despite the Si data showing that they failed at a significantly lower rate than Xi EndoWrists.[104]

126. And even when Intuitive considered an extended lives program for its Xi EndoWrists, revenue considerations were driving its analysis. For example, Intuitive conducted worst case and best case financial impact assessment on the extension of reprocessing cycles for instruments.[105] This document does not include a best and worst case safety assessment.

D. The use counter fails to independently verify the condition of the instrument. Hospital technicians must do an inspection to ensure that the instrument is safe.

127. The use counter itself does not provide any information about whether an instrument is safe to be used. The use counter does not indicate whether wires are frayed, whether scissors are dulled or broken, or whether there are other errors with the device. The only value on the use counter is how many times the instrument has been "used," i.e., attached to the robot and initiated in a movement.[106]

[103] DeSantis depo. tr., 173:2-17
[104] Duque 30(b)(1) depo. tr., 81 :8-12, 82 :5-24, 83 :3-19 ; Duque Ex. 247 (Intuitive-009657510) at 00967511, 00967513.
[105] Intuitive-00624804.
[106] Mahal Report at ¶¶ 65-66.

128. Rather than relying on the use counter, hospitals examine EndoWrists before surgery to determine whether they are safe for use.[107] When hospital technicians recognize issues with an EndoWrist, it will not be used in surgery.

129. Numerous instruments at Rebotix's facility that were received from hospitals and were ultimately deemed "Unsuitable for Repair" had remaining uses on the use counter. For example, the instruments I examined with broken cables all had remaining uses. The use counter would not prevent those instruments from being used in surgery.

VIII. ANY "DIFFERENCES" BETWEEN OTHER INSTRUMENTS REPAIRED BY SIS AND ENDOWRISTS DO NOT IMPACT SIS'S ABILITY TO REPAIR ENDOWRISTS

130. Dr. Howe opines that "any familiarity SIS has with maintenance and repairs to medical devices that use cables and pulleys, like flexible endoscopes, beds, and orthopedic limb holders, is insufficient to support the safety or reliability of the reset service Rebotix performed for SIS customers." Howe Report ¶ 15.

131. In support of that opinion, Dr. Howe discusses purported differences between the end uses of cabled instruments that SIS has previously repaired and the end use of EndoWrists, focusing on speed of operation and number of cable cycles for a typical use (Howe Report ¶¶ 39-41), exposure during reprocessing (Howe Report ¶¶ 41, 43), and the relatively small size of EndoWrist cables and pulleys (Howe Report ¶ 42).

132. There are numerous errors in Dr. Howe's comparison of different cabled instruments.

133. Dr. Howe speculates, without even discussing the respective reprocessing protocols or any other support, that the cables within EndoWrists are subject to more rigorous reprocessing

[107] Harrich depo. tr., 40:12-25, Donovan depo. tr., 33:23-34:9, 35:16-21.

than flexible endoscopes because "the [flexible endoscope] cable are contained entirely within the instrument and thus are not exposed to the harsh chemicals that cause damage." Howe Report ¶¶ 41, 43. However, flexible endoscopes may also be exposed to chemicals during reprocessing, for example, if the protective seal around the cables is damaged.[108] What is critical, and what SIS ensures for flexible endoscopes, is that a cable that has been reprocessed is inspected for wear such as corrosion, and then cleaned and repaired or tensioned if necessary.[109]

134. Dr. Howe focuses on the loading of EndoWrist cables (Howe Report ¶ 42), without ever addressing that the loading conditions of cables of flexible endoscopes, beds, and limb holders create conditions that EndoWrists typically do not experience. For example, while EndoWrist cables are typically actuated briefly for a series of movements, cables of a flexible endoscope have to accurately hold a position for an extended period of time and accurately navigate through tortuous anatomy. Moreover, flexible endoscopes have cables that are typically much longer than an EndoWrist cable, sometimes as long as six feet from the proximal controls to the distal tip. Further, flexible endoscope cables are angled through multiple unpredictable turns through the specific target anatomy for imaging and sample collection. While an EndoWrist cable may not be engaged for an entire surgery or even most of a procedure, the cables of a flexible endoscope may be in use throughout the procedure with varied strains and stresses for an extended period of time. The cables of beds and limb holders may undergo extreme and varied conditions as they are used for a variety of patients and situations, under less controlled conditions than an EndoWrist. These applications are all examples of long-term SIS experience in developing procedures and protocols for repair of a broad range of medical equipment and devices.

[108] Conversation with G. Posdal.
[109] Conversation with G. Posdal.

135. More importantly, all of these purported "differences" raised by Dr. Howe relate not to the suitability of the cables of the device at issue for repair, but rather to the manner in which they are used and thus the eventual causes of a condition that requires repair. As I discussed above, Intuitive's own procedures regarding cable tensioning are relatively simple, and the tensioning of EndoWrist cables during both Intuitive's initial assembly and the Rebotix repair process is properly performed with suitable tools and fixturing. In contrast, the tensioning of flexible endoscope cables requires disassembly, access and soldering in tight spaces.[110]

136. Based on my review of the Rebotix cable tensioning process and my understanding of the cable repairs that SIS performs on other devices, the cable repairs that SIS has previously performed provide an adequate background to perform the cable tensioning of the Rebotix repair process. For example, repair of cabling in flexible endoscopes involves inspection, testing, and cable tensioning in tight spaces.[111] The cable tensioning of an EndoWrist that I observed at Rebotix, and that Intuitive engineers describe, can be performed with basic tools and fixturing, and appropriate training, as discussed above. All of these various repair applications require the technician to follow specific, detailed protocols. SIS has extensive experience in this field.

137. The purpose of cable tensioning is to avoid the results of a cable being too tight or too slack. When a cable is too tight, the wheels on the bottom of the EndoWrist require additional torque to move the cables, resulting in unintuitive or rough motion. Similarly, when a cable is too slack, the EndoWrist cable system does not accurately transmit the motions from the surgeon console to the end of the EndoWrist instrument, resulting in unintuitive motion. The only reason for identifying a specified tension number for the cable is that the tension value generally correlates to a device that is not exhibiting the results of the drive cable being too slack or too tight. However,

[110] Conversation with G. Posdal; SIS357887-SIS357893.
[111] Conversation with G. Posdal

it is the condition of the cable that matters, not the number itself. Adjusting to a number is only a sign that the tension is likely correct; it does not assure that the too tight or too slack conditions are not occurring. The only way to determine whether too tight or too slack conditions are occurring is to directly test for those conditions on each device. The Rebotix repair process performs this evaluation on each device.

138. The Rebotix repair process directly tests the result of the cable tension to see that the conditions that would result from the drive cable being too tight or too slack are not present.

139. Moreover, Rebotix confirmed that its cable tensioning procedures were appropriate during its extensive EndoWrist testing. In its original testing, Rebotix determined the desired range for the no load torque values for the mechanical wheels at the bottom of the EndoWrist and quantified each of those values. Rebotix's life testing protocols established calibration of the instrument's no-load torque for each drive wheel in both clockwise and counterclockwise directions, and specified the range of motion of each EndoWrist wheel. In the image below, Rebotix discusses calibration for each mechanical wheel on the EndoWrist (identifying specific values) and describes the mechanical degree of freedom expected of the jaws of the device.

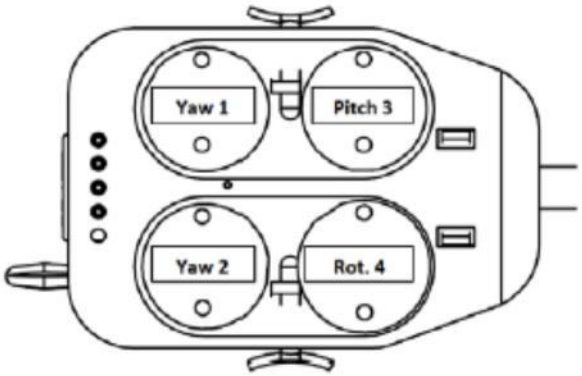


Figure 1

mechanical_wheel_no_load_torque_yaw_2

The no load torque of the Yaw 2 wheel shall be calibrated to 3.0 – 7.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 1 for identification of the Yaw 2 wheel.

mechanical_wheel_no_load_torque_pitch_3

The no load torque of the Pitch 3 wheel shall be calibrated to 3.0-6.8 in. oz f. of torque in the clockwise wheel rotation. The no load torque of the Pitch 3 wheel shall be calibrated to 4.2-10.7 in. oz f. of torque in the counter-clockwise wheel rotation. Refer to figure 1 for identification of the Pitch 3 wheel.

mechanical_wheel_no_load_torque_rotation_4

The no load torque of the Rotation 4 wheel shall be calibrated to .25-2.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 1 for identification of the Rotation 4 wheel.

mechanical_degree of freedom_yaw

The jaws of the device shall move freely (without binding or slipping) in the Yaw directions (clockwise and counter-clockwise) to the tool clevis mechanical stops (See Figure 2) when the Yaw 1 and Yaw 2 wheels are rotated in both directions.

REBOTIX170067

140. The PR3052 Spool Torque SOP shows the different no load torque values specific to each EndoWrist's clockwise and counter-clockwise wheel movement.

Ref	EndoWrist	Yaw 1 in. oz f.		Yaw 2 in. oz f.		Pitch 3 in. oz f.		Rotation 4
		Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Both Ways
420001	Potts Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420006	Large Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420007	Round Tip Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420036	Debakey Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420048	Long Tip Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420049	Cadiere Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420093	ProGrasp Forceps	2.0 - 4.6	2.4 - 5.6	2.0 - 4.0	2.6 - 5.0	2.0 - 6.5	4.3 – 9.7	.25 – 2.0
420110	Precise Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420171	Micro Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420172	Maryland Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420178	Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420179	Monopolar Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420181	Resano Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420183	Permanent Cautery Hook	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420184	Permanent Cautery Spatula	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420189	Double Fenestrated Graspers	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420190	Cobra Grasper	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420194	Mega Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420205	Fenestrated Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420207	Tenaculum Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420227	PK Dissecting Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420296	Large SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420309	Mega SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420344	Curved Bipolar Dissector	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0

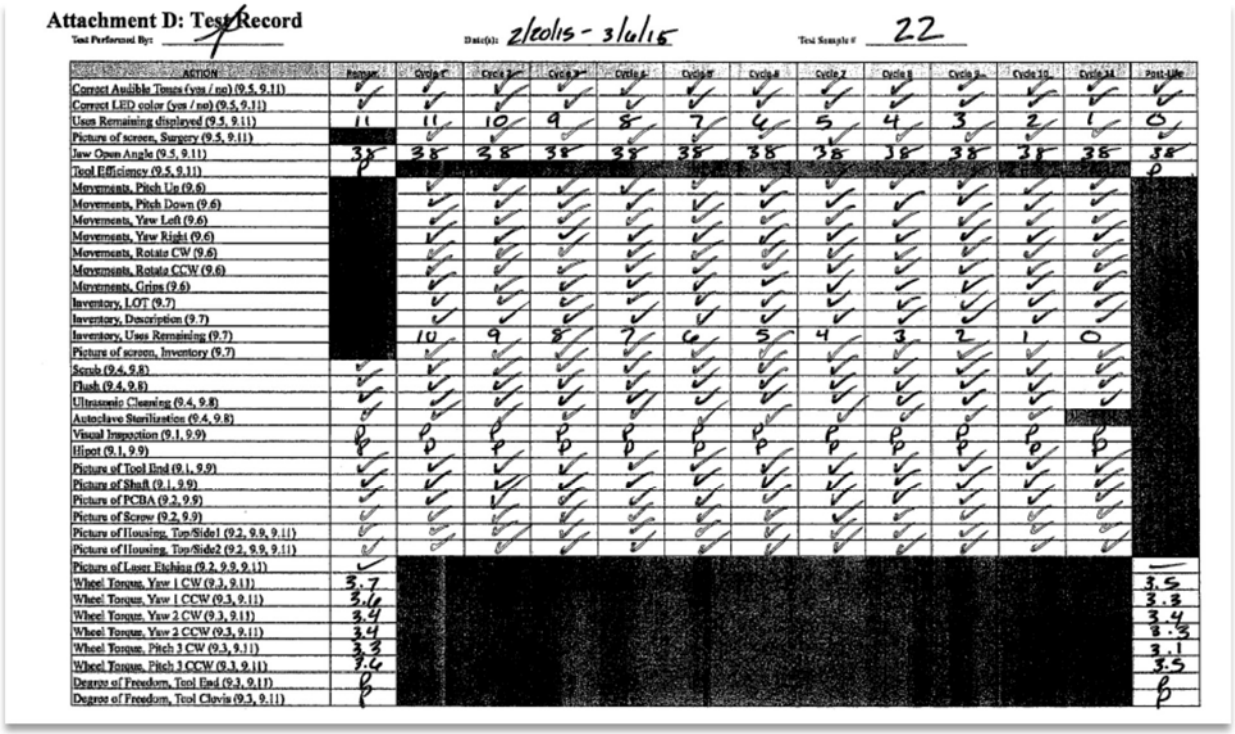
Table 1

PR3052 – Wheel No Load Torque; REBOTIX133349

141. As part of that testing of wheel no load torque values, Rebotix examined the cable tension that is required to achieve the desired intuitive motion of each EndoWrist. And Rebotix concluded that when it tightened the cables enough to remove the slack from the cables, the wheel torque values were in an acceptable range, and more importantly, its repaired EndoWrists functioned equivalently to new EndoWrists sold by Intuitive.[112]

[112] Fiegel conversation, *see also* REBOTIX124900-REBOTIX124923, REBOTIX120686.

142. Rebotix then tested wheel no load torque values over multiple uses to determine whether those values were altered by any cable tension issues. For example, in the second round of life testing (life testing performed on instruments that had already been repaired by Rebotix once), Rebotix measured wheel no load torque values on each of the tested EndoWrists to ensure that they were within an acceptable range after an additional eleven uses. And the wheel torque values exhibited what Rebotix also verified during its manual testing: the instrument cables performed their function and each EndoWrist moved intuitively.



Attachment D: Test Record

Test Performed By: [redacted] Date(s): 2/20/15 - 3/6/15 Test Sample #: 22

ACTION	Receipt	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Post-Life
Correct Audible Tones (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Correct LED color (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Uses Remaining displayed (9.5, 9.11)	11	11	10	9	8	7	6	5	4	3	2	1	0
Picture of screen, Surgery (9.5, 9.11)	[redacted]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jaw Open Angle (9.5, 9.11)	38	38	38	38	38	38	38	38	38	38	38	38	38
Tool Efficiency (9.5, 9.11)	P	[redacted]											P
Movements, Pitch Up (9.6)	[redacted]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	[redacted]
Movements, Pitch Down (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Left (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Right (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CCW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Grips (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, LOT (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Description (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Uses Remaining (9.7)		10	9	8	7	6	5	4	3	2	1	0	
Picture of screen, Inventory (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Scrub (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Flush (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ultrasonic Cleaning (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Autoclave Sterilization (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	[redacted]	
Visual Inspection (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Hipot (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Picture of Tool End (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Shaft (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of PCBA (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Screw (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side1 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side2 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Laser Etching (9.2, 9.9, 9.11)	✓	[redacted]											—
Wheel Torque, Yaw 1 CW (9.3, 9.11)	3.7												3.5
Wheel Torque, Yaw 1 CCW (9.3, 9.11)	3.6												3.3
Wheel Torque, Yaw 2 CW (9.3, 9.11)	3.4												3.4
Wheel Torque, Yaw 2 CCW (9.3, 9.11)	3.4												3.3
Wheel Torque, Pitch 3 CW (9.3, 9.11)	3.3												3.1
Wheel Torque, Pitch 3 CCW (9.3, 9.11)	3.6												3.5
Degree of Freedom, Tool End (9.3, 9.11)	P												P
Degree of Freedom, Tool Clevis (9.3, 9.11)	P												P

REBOTIX132562

Attachment D: Test Record

Test Performed By: [redacted] Date(s): 2/20/15 - 3/6/15 Test Sample #: 21

ACTION	Remove	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Post-Life
Correct Audible Tones (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Correct LED color (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Uses Remaining displayed (9.5, 9.11)	11	11	10	9	8	7	6	5	4	3	2	1	0
Picture of screen, Surgery (9.5, 9.11)	[redacted]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jaw Open Angle (9.5, 9.11)	36	38	38	39	38	38	38	39	39	38	38	38	36
Tool Efficiency (9.5, 9.11)	1	[redacted]											P
Movements, Pitch Up (9.6)	[redacted]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	[redacted]
Movements, Pitch Down (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Left (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Right (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CCW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Grips (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, LOT (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Description (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Uses Remaining (9.7)		10	9	8	7	6	5	4	3	2	1	0	
Picture of screen, Inventory (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Scrub (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Flush (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ultrasonic Cleaning (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Autoclave Sterilization (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	[redacted]	
Visual Inspection (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Hipot (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Picture of Tool End (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Shaft (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of PCBA (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Screw (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side1 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side2 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Laser Etching (9.2, 9.9, 9.11)	✓	[redacted]											✓
Wheel Torque, Yaw 1 CW (9.3, 9.11)	3.7												3.7
Wheel Torque, Yaw 1 CCW (9.3, 9.11)	3.4												3.4
Wheel Torque, Yaw 2 CW (9.3, 9.11)	3.6												3.5
Wheel Torque, Yaw 2 CCW (9.3, 9.11)	3.1												3.7
Wheel Torque, Pitch 3 CW (9.3, 9.11)	3.8												3.7
Wheel Torque, Pitch 3 CCW (9.3, 9.11)	3.9												3.6
Degree of Freedom, Tool End (9.3, 9.11)	P												P
Degree of Freedom, Tool Clevis (9.3, 9.11)	P												

REBOTIX132559

IX. SIS PROPERLY RELIED ON THE EXPERTISE OF ITS TRUSTED TECHNOLOGY PARTNER, REBOTIX

143. Dr. Howe faults SIS because it "did no independent testing of the EndoWrist instrument reset [*sic,* repair] process and instead relied on Rebotix's testing." Howe Report at ¶ 44. According to Dr. Howe, "[w]ithout access to the details of Rebotix's risk management process and testing results, SIS's claim that '[a]fter service by SIS, the surgical device or instrument is returned to the customer for its original intended use . . . and the surgical device or instrument is returned to its original safety and effectiveness' is not supportable or reasonable." *Id*. As discussed below, SIS properly relied on the testing of its trusted technology partner, Rebotix, regarding the EndoWrist repair process.

144. SIS is an independent service organization or "ISO." It has direct relationships with hundreds of hospitals and hospital purchasing organizations throughout the country, and acts as an arm of hospitals by providing repair and servicing of instruments and devices. It directly interfaces with hospitals to collect, track, and repair instruments and devices, sometimes at the hospital using mobile equipment and sometimes at its own facilities.[113]

145. SIS has a long-standing relationship with the principals of Rebotix spanning at least 20 years.[114] While SIS directly interfaces with hospitals and performs many repairs itself, it partners with trusted technology providers such as Rebotix and other companies run by the principals of Rebotix (such as Benjamin Biomedical) to develop processes and technologies used in its business. For example, SIS has worked with the principals of Rebotix on technologies such as harmonic scalpels, phacoemulsifiers, and video-cameras.[115] The SIS relationship with Rebotix followed this pattern, with Rebotix developing the underlying Interceptor technology and

[113] Posdal 30(b)(1) depo. tr., 11:17-12:1, 15:1-3.
[114] Conversation with G. Posdal.
[115] Conversation with G. Posdal.

EndoWrist repair process, and SIS initially working as a distributor through its extensive hospital contacts.[116]

146. Although SIS was initially working with Rebotix as a distributor, collecting EndoWrists from hospitals for repair by Rebotix and then returning the repaired instruments to the hospitals, Rebotix and SIS were in negotiations for SIS to perform the repairs at its own facilities, with Rebotix providing SIS with Interceptor chips and detailed procedures for repairing EndoWrists. SIS visited Rebotix to observe its repair procedures, and Rebotix performed repairs at an SIS facility with a major EndoWrist repair customer, Banner Health.[117]

147. As a technology provider in active negotiations to share a process it had developed, it would not make sense for Rebotix to provide SIS with the technical details of its testing or repair procedures. Prematurely providing this type of technical detail would result in the possible loss of valuable intellectual property rights. On the other hand, in view of SIS's in-person meetings and extensive history working with the principals of Rebotix as technology providers, it was reasonable for SIS to believe that Rebotix was truthful about its testing and processes, and that this testing and processes were robust.

148. Dr. Howe faults SIS for relying on the "Summary of Quality and Reliability Measures" document. Howe Report at ¶ 45. But as Dr. Howe admits, that document provides a "listing of the processes, standards, and tests" including that "A detailed FMEA (Failure Modes and Effects Analysis) was performed covering the service process."[118] *Id.* ¶ 46. Dr. Howe acknowledges that this document also explained that (a) Rebotix performed "formal life testing to establish reliability" (*Id.* ¶ 47), (b) Rebotix performed "A worst-case analysis . . . to determine

[116] Posdal 30(b)(6) depo. tr., 22:23-23:22, 66:20-67:8; K. Johnson 30(b)(6) depo. tr., 22:12-24, 23:7-25.
[117] Posdal 30(b)(1) depo. tr., 28:13-29:24, 30:5-15; K. Johnson 30(b)(6) depo. tr., 33:9-18.
[118] Def.'s Ex. 136, SIS095115-095139

which models should be used during performance and life testing" (Howe Report at ¶ 49), (c) "a smaller batch of representative models were subjected to over 50 cleaning and sterilization cycles to demonstrate the robust nature of the instrument's design" (*Id*. ¶ 50), and (d) "over two dozen industry standards" were "considered and applied to the development process" (*Id*. ¶ 51).

149. Not only was SIS entirely reasonable in relying on these representations by a long-trusted technology partner, but Rebotix's representations were truthful and its testing and procedures extremely robust, as discussed below.

A. Reverse Engineering to Develop Specifications

150. In my experience, reverse engineering the original specifications of an instrument is a common practice used by mechanical engineers in understanding instruments and their functions. Original specifications for instruments are often not published, and repair companies seeking to return an instrument to its original specifications need to conduct a thorough reverse engineering process. Reverse engineering typically involves two steps: testing a new instrument to understand and establish its specifications, and then testing a repaired or serviced instrument to ensure that it functions in the same manner as a new instrument. Rebotix performed these steps in its initial testing.

151. Before servicing EndoWrists, Rebotix extensively tested new EndoWrists to establish the baseline specifications for EndoWrists. As part of that complete evaluation, Rebotix assessed cable tension, wheel torque values, scissor sharpness, grasper alignment, insulation strength, and motion handling by the instrument.[119] This process represented a significant effort by Rebotix and was completed over the course of twelve to eighteen months.[120]

[119] Fiegel conversation, *see also* REBOTIX075431-075433, REBOTIX075420, REBOTIX089137.
[120] Fiegel conversation.

152. And Rebotix documented the test results in a series of specification documents.[121] Those documents are used during Rebotix's repair process to ensure that the instruments comport with Intuitive's specifications.

153. After Rebotix documented the original specifications and developed its repair process, it employed third party testing laboratories to verify that its repaired EndoWrists complied with all applicable safety standards. Rebotix sent its repaired EndoWrists to SGS for electrical safety testing,[122] and IMR Test labs for materials testing.[123] And Rebotix then had its entire service process evaluated by DQS-Med to confirm that it complied with all applicable safety standards.[124]

154. The result of this robust initial reverse engineering process and subsequent testing is a repair process that safely and effectively ensures that repaired EndoWrists can continue to be used by hospital customers.

B. Risk Management

1. Risk management related to wear and tear

155. Dr. Howe contends that the Rebotix repair process does not "adequately address the effects of wear and tear that accrue during instrument usage." (Howe Report at ¶ 14). His opinion is wrong and misleading in at least two respects. First, as I stated earlier, Intuitive's use counter itself in no way "adequately addresses the wear and tear that accrue during instrument usage."

156. Second, Rebotix does consider "wear and tear" suffered by instruments beyond the original number of uses.

[121] REBOTIX133235- REBOTIX133311, REBOTIX133337- REBOTIX133353, REBOTIX133373.
[122] REBOTIX128851.
[123] REBOTIX092208.
[124] REBOTIX083098.

157. In fact, Rebotix explicitly considers tear in its initial inspection of the instrument. Based on that inspection, any "tear" or breakage suffered by an instrument prior to Rebotix receiving it renders it ineligible for repair. For example, EndoWrist instruments with broken scissors, snapped graspers, or frayed cables will not be repaired by Rebotix.

158. As I discussed in detail, Rebotix's repair process also accounts for any wear that the instrument has experienced. For example, it accounts for the dulling of scissors or the misalignment of graspers as well as any loss of tension in cables through the cable tensioning process and drive wheel torque evaluation. Rebotix's life testing confirms that the instrument continues to operate just as a new EndoWrist would through its additional lives.

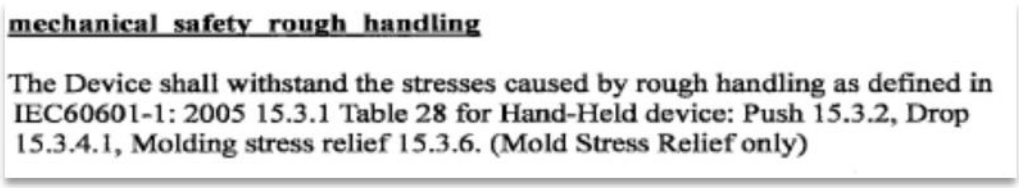
159. Rebotix seriously considered all potential failure modes of EndoWrists in its design plan and testing. In its risk management documents, Rebotix concluded that any increase in "any estimated hazard severity or probability of occurrence" would need to be investigated and mitigated.[125] To that end, Rebotix conducted extensive life testing to ensure that its repaired EndoWrist instruments continued to operate and function in the same manner as new Intuitive EndoWrists. Rebotix's life testing confirmed that its repairs resulted in no increase in hazard severity or probability of occurrence.

C. Life Testing

160. Rebotix specifically performs numerous tests to expose instruments to excessive mechanical forces.

161. For example, in Rebotix's life testing, the following mechanical safety instruction is included in each of the testing procedures:

[125] REBOTIX123794.


mechanical_safety_rough_handling

The Device shall withstand the stresses caused by rough handling as defined in IEC60601-1: 2005 15.3.1 Table 28 for Hand-Held device: Push 15.3.2, Drop 15.3.4.1, Molding stress relief 15.3.6. (Mold Stress Relief only)

REBOTIX132477

162. And Rebotix further ensures that the instruments are subjected to the same mechanical strains they would face during surgery. During life testing, Rebotix ensured that instruments are tested in a manner that corresponds with surgical use. The graspers were tested for their ability to successfully grasp tissue,[126] scissors were tested to successfully cut tissue,[127] and the electrosurgical instruments were tested to successfully cauterize tissue.[128] And each instrument's range of movement was tested in every direction—pitch, yaw, and rotation.[129]

163. To determine how many times each instrument should be tested in this way for each use, Rebotix surveyed a number of surgeons to establish the "high end number of manipulations/activations for any given function of the EndoWrist surgical tool end."[130] Rebotix established that this high-end number was 60 activations.

164. Rebotix then performed each separate part of its testing 72 times. Each instrument was manipulated in each direction 72 times per use. It grasped, cut, or cauterized tissue 72 times per use (using chicken breast as simulated tissue). Because Rebotix performed 11 life tests, each tool was required to pass 792 test interactions with the chicken breast.[131]

[126] REBOTIX170283-REBOTIX170284.
[127] REBOTIX170075-REBOTIX170076.
[128] REBOTIX170077-REBOTIX170078.
[129] REBOTIX170075.
[130] REBOTIX170053.
[131] *See, e.g.*, REBOTIX170075.

165. This testing reflects the mechanical wear that an instrument will experience during surgery, and tests even above the high-end number of manipulations from the surgeon survey for an instrument to ensure that the instrument can be safely used.

166. Intuitive's life testing is on new EndoWrist instruments and does not take into account the possibility of repair. Intuitive has never conducted any life testing on an instrument after that instrument has been repaired.[132] For example, Intuitive has never determined the likelihood of cable failures after re-tensioning. These differences mean that life testing by Intuitive and life testing by Rebotix cannot be directly compared.

1. Statistical analysis for number of uses

167. Rebotix performed its life testing using statistical analysis by using a specified number of samples to establish a particular level of reliability. Rebotix initially identified the worst-case instruments that were expected to experience the highest loads and that were most likely to fail testing. A worst-case model "means that no other [Endo]Wrists represent a greater risk of failure."[133] When selecting the EndoWrists that would undergo testing, Rebotix considered which of the EndoWrist tool ends would suffer the highest stresses from surgery, and selected representative models that would test each different tool type.[134] Intuitive also uses worst-case testing for its testing of EndoWrists.[135]

168. The Rebotix life testing protocols selected 22 samples of each of the identified worst case models of EndoWrists for testing "to provide the level of statistical significance at 90% confidence of 90% reliability when no failures are observed."[136] None of the samples that Rebotix

[132] Duque 30(b)(1) depo. tr., 149:9-151:8; DeSantis depo. tr., 210:15-212:1.
[133] REBOTIX146771.
[134] *Id*.
[135] Duque 30(b)(6) depo. tr., 66:12-68:7; Duque Ex. 269 (Intuitive-00290826).
[136] REBOTIX170058.

tested for any of the instruments produced a failure, satisfying the desired level of statistical confidence.

2. Rebotix's safety margin

169. Rebotix performed reprocessing cycles after each simulated surgical use cycle to model the stresses that the device would experience from reprocessing.[137] And, as discussed below, because Rebotix conducted two rounds of life testing, it exposed instruments to at least 20 additional reprocessing cycles. None of the instruments experienced failure over the course of those reprocessing cycles.

170. The Rebotix life testing assumes the proper inspection and servicing of instruments every ten uses. One round of the Rebotix life testing involved instruments that had already been used for nine uses, then were repaired by Rebotix and subjected to a further life testing for eleven uses. Rebotix also performed a second set of tests on instruments that had already been repaired by Rebotix and then tested them for a further ten life test cycles.[138] As part of that testing, Rebotix again performed the steps of its inspection and repair process before conducting the continued testing. The Rebotix results verified that after repair, the instruments did not experience failures in the additional set of ten uses.[139]

171. These results demonstrate that with proper inspection and repair after every ten uses, EndoWrist instruments can continue to be used safely. Intuitive's life testing does not take these regular inspections and repairs into account.

T. Kim Parnell, Ph.D., P.E.

Dated: January 18, 2023

[137] REBOTIX170053.
[138] REBOTIX132019
[139] *Id.*

ATTACHMENT A

***Curriculum Vitae* of T. Kim Parnell**

T. Kim Parnell, PhD, PE

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Sunnyvale, CA 94087

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Expertise Highlights

- Medical device/biotechnology – Cardiovascular, Orthopedic, Orthodontic
- Patents & Intellectual Property
- Product Liability; Personal Injury
- Bluetooth, Zigbee, Wireless technology
- System Specifications & Test Procedures
- Composite Materials Design & Damage;
- Plastics, Molding, Manufacturing
- Telephone set design; touchpads; keypads
- Piezoelectric components
- Consumer Electronics & Products
- Laptop computers; keyboards; displays
- Materials & Metallurgy
- Failure Analysis & Reliability
- Fracture & Fatigue
- Numerical Multi-Disciplinary Analysis
- Digital Twin Technology Applications
- User experience & system interaction
- User interface design
- Finite Element Analysis of Structures & Fluid/Heat Transfer (FEA/CFD)
- Structural Mechanics, Fluid Mechanics, Heat Transfer, Thermodynamics
- Transducers, Accelerometers, MEMs
- Software design, development, QA
- Green energy: Wind, Solar Trackers, PV Panels; Electric Vehicles, Battery tech
- Shock & Vibration Sensitivity
- Vehicle & Heavy-Truck Crashworthiness
- ATV & Vehicle Design, Crashworthiness
- Group Manager & Project Leader;
- Strategic & Budgetary Planning responsibility
- Simulation Data Management

Education

Year	University	Degree Awarded
1984	Stanford University	Ph.D., Mechanical Engineering
1979	Stanford University	MSME, Mechanical Engineering
1978	Georgia Tech	BES, Engineering Science & Mechanics (Highest Honors)
2004	San Jose State University	Silicon Valley Executive Business Program (SVEBP)

Ph.D. Thesis: "Numerical Improvement of Asymptotic Solutions and Nonlinear Shell Analysis", June, 1984.

Professional Associations and Achievements

- Registered Mechanical Engineer (PE, M025550) in the State of California
- ASME Fellow; American Society of Mechanical Engineers (ASME)
- IEEE Senior Member; Institute of Electrical and Electronics Engineers (IEEE)
- Society of Automotive Engineers (SAE), Member
- ASM International Member; SMST (Shape Memory and Superelastic Technologies) Member; EDFAS (Electronic Device Failure Analysis Society) Member
- IEEE-SCV Santa Clara Valley Section Leadership Award; 2018
- IEEE Santa Clara Valley (IEEE-SCV) Section; Chair-2011, Vice Chair-2010
- IEEE Consultants' Network of Silicon Valley (IEEE-CNSV), Board Member; Chair: 2008-2009
- NAFEMS Member – Composite Materials Working Group (CWG), Vice-Chair
- IEEE Vehicular Technology Society (IEEE-VTS); Vice-Chair, 2012-2018; Treasurer 2018-present
- IEEE Consumer Electronics Society (IEEE-CE), IEEE Computer Society, IEEE Engineering in Medicine & Biology (IEEE-EMBS), IEEE Electronics Packaging Society (IEEE-EPS)
- Reviewer: *Journal of Composite Materials (JCM); International Journal of Forensic Engineering (IJFE); International Journal of Technology Transfer and Commercialization (IJTTC).*
- Chinese American Semiconductor Professional Association (CASPA)

Employment History

From: 2000 **Parnell Engineering & Consulting (PEC)**
To: Present Sunnyvale, CA; Web: *parnell-eng.com*
Position: *Principal & Founder*

Provides independent engineering consulting & expert witness services for high-technology applications including:

- Medical device/biotech product development & concept design
- Medical device cardiovascular applications across wide product range
- Medical device orthopedic, spinal, prosthetic devices – IP, design
- VC technical due-diligence for prospective medical device investment
- Patent & intellectual property – litigation, IPR, research, due diligence
- Expert Witness & Litigation Support services – multiple technologies
- Nitinol, shape-memory applications; biomaterials applications
- Portable devices, keypads: robust design, reliability & durability
- Cell phone Li-Ion battery failure & fire; protective enclosures;
- Bluetooth, Cellular, Zigbee, Wireless technology
- Solar panel tracker technology; PV Panel technology
- Manufacturing technology; materials applications (metals, polymers)
- Reliability and failure analysis services; accelerated testing
- Research in application & damage of composite materials
- Teaching intensive workshops & training seminars on simulation, design, and reliability for practicing engineers
- Lecturer in Prof. Steve Tsai's *Stanford Composites Design Workshop*
- Composite materials design & applications
- Wind Energy, Solar Energy, Alternative Energy – technology
- Electric vehicles, battery systems: design & development
- Heavy-Truck Rollover, Vehicle & ATV Crashworthiness; Barriers
- Software design, development, user experience, QA, testing
- Applications of CAE, FEA, and High-Performance Computing (HPC)
- Digital Twin Technology—FEA Simulation & Test

From: 2010 **Santa Clara University**
To: 2012 Santa Clara, CA
Position: *Faculty, Mechanical Engineering Department*

Taught courses covering a range of topics including Materials Science, Manufacturing Methods, Composite Materials, Finite Element Methods, Mechanism Dynamics, Computer Graphics, & Design. Advised students on Design, Safety, and Simulation for Student Projects including SAE Formula-Hybrid Vehicles. Research in Composite Materials and High-Performance Computing. Interaction with Industry Advisory Board (IAB) & ABET Certification. Teamed with other faculty for strategic initiatives and equipment/tool grants for research. Promote IEEE, ASME, cross-disciplinary initiatives & social media avenues for student networking, professional development & project support.

From: 2006 **MSC Software Corporation**
To: 2010 Sunnyvale, CA
Position: *Senior Manager, User Experience; Lead Application Engineer*

Integrated feedback from customers into user interface design & specifications; Beta testing of prototypes with users; CAE software Product Management role for user interface and analysis tools including:

- Product quality, testing, and improvement; drove customer satisfaction
- Application of advanced analysis technology in design & manufacturing
- Led corporate Wind Energy initiative & revival of Fatigue product
- Composite materials – acknowledged corporate & customer expert
- Customer training courses, workshops, webinars; developed & taught
- Software design, development, QA, testing of commercial apps
- Mentoring and development of junior staff; interviewed & hired staff for India; developed and trained staff using distance learning

Applied finite element technology to applications including automotive, medical device, energy, and electronics. Created customer satisfaction via:

- Customer support & analysis process development; Digital Twin
- Material testing & data reduction for development of properties

From: 1999 **Rubicor Medical, Inc.**
To: 2000 Redwood City, CA
Position: *Director of R&D*

Led the R&D team for this start-up medical device company developing breast diagnostic and therapeutic devices. Designed device considering interaction of Physician with Device and human factors. System included a mechanical subsystem and RF generator/control electronics. Developed initial prototypes and conceptual designs; researched IP and competing technologies.

From: 1986 **Exponent, Inc. and Failure Analysis Associates (FaAA)**
To: 1999 Menlo Park, CA
Position: *Senior Managing Engineer*

Delivered consulting services for failure analysis, accident investigation, product liability, patent/IP, insurance-related litigation, medical device and biotechnology product development, FDA submission, and forensic/failure investigation. Performed analyses involving stress, thermal, & fluid applications; testing of material properties and use of laboratory techniques such as SEM & Optical Microscopy for inspection of material samples. Led the SAE Heavy Truck Crashworthiness, Phase II project with testing & simulation of heavy-truck cabs in rollovers. Managed the Engineering Analysis Group and had profit/loss responsibility for the Engineering Computer Center. Maintained high personal utilization/billable hours and had increasing personal/group profitability with consulting services revenue generation >$600K.

From: 1995 **Stanford University**
To: 1996 Stanford, CA
Position: *Visiting Associate Professor, Mechanical Engineering Department*

Taught graduate courses in Theory of Plates and Theory of Shells in the Applied Mechanics Division (now Mechanics & Computation) of Mechanical Engineering. Part-time appointment while full-time staff-member at Exponent.

From: 1984 **SST Systems, Inc.**
To: 1986 Sunnyvale, CA
Position: *Principal Engineer in Pressure Vessels, Piping & Structures Division*
Managed software development, facilitated university collaboration, developed product specifications and enhancements based on customer feedback, supported and trained over 30 new customers, and created standardized product documentation. Provided sales and technical marketing support to CEO during product launch; formulated go-to-market campaign.

From: 1980 **Stanford University**
To: 1984 Stanford, CA
Position: *Research Assistant, Mechanical Engineering Department*
Established the theoretical basis and developed computational tools for nonlinear shell mechanics. Emphasized computational mechanics and engineering applications, including linear & nonlinear finite element methods and other numerical analysis techniques. Algorithm & software development

From: 1978 **AT&T Bell Laboratories**
To: 1980 Indianapolis, IN
Position: *Member of Technical Staff (MTS), Physical Design Group*
Design, development, and manufacturing of high-volume telecommunication components. Researched and designed dials, keypads, electromechanical systems, and piezoelectric polymer applications. Employed range of materials including elastomers, metals, polymers, and piezoelectrics for keypad and transducer applications. Emphasis on cost, reliability, and manufacturing simplicity. Developed new technologies to ultimately drive field improvements. Applied finite element simulation to improve designs and reduce prototypes.

From: 1976 **General Motors Corporation**
To: 1977 Atlanta, GA
Position: *Engineering Assistant, Plant Engineering Department*
Production line design and manufacturing applications for the GM Lakewood assembly plant. Supervised demolition and production line installation during changeover. Installed automated spotweld robot for sheet metal panels. Studied automotive manufacturing & assembly operations from start to finish.

Selected Grants & Research Programs

SA Photonics, Inc.

- 2013 – Phase I Navy SBIR – Post-IED Hull Inspection Tool, Topic N123-156

Stanford University

- 2012 – Phase II Army SBIR – Development and Implementation of Micro-Mechanics of Failure (MMF) Model for Composites in Commercial Finite Element Codes

Santa Clara University

- 2012 – Kuehler Summer Undergraduate Research Grant – student support for composite materials testing & characterization
- 2011 – Technology Innovation Grant – Acquisition of advanced DSC/TGA System for improved lab capability
- 2011 – Technology Innovation Grant – Acquisition of High-Performance Workstation for advanced simulation of large dynamic and nonlinear systems
- 2011 – Technology Innovation Grant – Materials Laboratory equipment upgrades and reorganization

Selected Presentations

"SMA Seismic Damping Devices: Fabrication, Testing, Analysis, and Projections", SMST-2014, Monterey, CA, May, 2014.

"Mechanical Design for Reliability: What does it Mean?", ASME Santa Clara Valley Section, Sunnyvale, CA, Mar, 2014.

"Prosthetic Feet using Carbon Fiber Composites: Design, Simulation, & Testing", ASME Santa Clara Valley Section, Jun, 2013.

"Mechanical Design for Reliability: Beating the Tough Problems", IEEE-SCV Reliability Society, Santa Clara, CA, Jun, 2013.

"Prosthetic Feet using Carbon Fiber Composites: Design, Simulation, & Testing", MSC Software 50th User Conference, Irvine, CA, May, 2013.

"Composite Materials: Improved Understanding of Composite Failure Mechanisms with DIC Testing & Analysis", Trilion User Conference, Philadelphia, PA, Sep, 2012.

"Medical Device Failures – 'Not so Good, Very Bad, and Truly Ugly'!!", ASM (Materials Information Society) Santa Clara Valley Chapter, May, 2012.

"C-Ply Bi-Angle NCF Tape Seam Assessment & Design Considerations for Automated Tape Laying", Composites Design Forum, JEC Composites Conference, Paris, Mar, 2012.

"Failure of Structures Designed with Composite Material – Delamination", *'Meet the Experts' Forum on Composite Materials*, Joint with Prof. Steve Tsai, SMP Tech, Feb 28, 2012.

"Shape Memory Alloy Fundamentals & Advanced Simulation Techniques for Medical Products", *'Meet the Experts' Forum on Nitinol Properties and Unique Behavior for Medical Product Design*, SMP Tech, Sep 14, 2011.

"Stiffness and Strength of Laminates Fabricated with Bi-Directional Tape", ICCM-18 (International Conference on Composite Materials, Korea, Aug, 2011, (with Daniel D. Melo & Christine Tower))

"Composite Materials – Damage & Delamination", Santa Clara University, Mechanical Engineering Seminar, Feb, 2011

"Composites Damage, Delamination, Failure & Curing" and "Workshop on Mic-Mac/FEA" with Prof. Steve Tsai, Stanford Composites Design Workshop, 2010-2012

"Composite Damage, Delamination, and Failure" and "Workshop on Mic-Mac/FEA" with Steve Tsai, Stanford Composites Design Workshop, Jan, 2010

"Composite Failure Methods – Application Comparisons", Composites Durability Workshop-14 (CDW-14), UCLA, Jul, 2009

"Composites Damage, Delamination, and Failure Analysis", Stanford Composites Workshop, May 2009

"Finite Element Analysis using a Thermomechanical Shape Memory Alloy Model", SMST-2006, Monterey, CA, 2006.

"Medical Device Issues & Trends", in "Biomedical Wave: Opportunities for Non-Biologists**",** MedTech Bridge Seminar Series, 2005.

"Medical Device Development and Entrepreneurship", IEEE Consultants' Network of Silicon Valley (IEEE-CNSV), *www.CaliforniaConsultants.org* , 2004.

"CFD Fundamentals and Applications in Biotechnology", ASME Professional Development Seminar, 2003 & 2004.

"Medical Device Business Opportunities in China", multiple presentations to key government and industry representatives, CASPA Delegation, Oct, 2003.

"Using Simulation with Testing for Maximum Benefit", WESCON 2003, Low Cost Tools: Alternatives for Problem Solving in Development, Design and Application, San Francisco, CA, Aug, 2003.

"Fracture Mechanics: Overview and Applications", Aeronautics & Astronautics Department, Stanford University, May, 1999.

"Integrated Fluid/Thermal/Structural Analysis of a Turbine Blade", American Society of Mechanical Engineers Bay Area Technical Conference, May, 1995.

"Failure Analysis Projects", Mechanical Engineering Department, Stanford University, May. 1992.

"Finite Element Applications in Failure Analysis", Mechanical Engineering Department, Stanford University, Mar, 1991.

"Soil-Pipeline Interaction Associated with a Process-Plant Explosion", Seminar in Solid Mechanics, Stanford University, Nov, 1989.

"*Typical* Failures: Causes and Consequences", Construction Engineering and Management Program, Civil Engineering Department, Stanford University, 1989.

"Shell Analysis Using Personal Computers", Solid Mechanics Seminar, Stanford University, 1985.

Selected Publications

"Numerical evaluation of SMA-based multi-ring self-centering damping devices.", (2021). Smart Materials and Structures. DOI: *https://doi.org/10.1088/1361-665X/ac1d94*. (with M. Salehi, R. DesRoches, and D. Hodgson).

"Numerical Simulation of Seismic Response Control of Frame Structure Using High-Temperature Shape Memory Alloy Wire"; Proceedings of: International Conference on Earthquake Engineering (SE-50EEE), At MAEE, Skopje, Macedonia, May 2013, (with Md. Golam Rashed and Raquib Ahsan).

"Equivalent Properties for Finite Element Analysis in Composite Design", JEC Composites Magazine, No.68 (Bi-Angle NCF Special Issue), Oct, 2011, (with Stephen W. Tsai)

"Stiffness and Strength of Laminates Fabricated with Bi-Directional Tape", ICCM-18, Aug, 2011, (with Daniel D. Melo & Christine Tower)

"How Reliable Is Your Product: 50 Ways to Improve Product Reliability", Mike Silverman, 2011 (2-Book Chapters contributed by T. Kim Parnell).

"Heavy Truck Roll Cage Effectiveness", IMECE2009-12423, Proceedings of IMECE: ASME-Mechanical Engineering Congress and Exposition, Nov, 2009, (with Stephen Batzer, Bruce Enz, Grant Herndon, Chandrashekar Thorbole, Robert Hooker, and Mariusz Ziejewski).

"Composite Failure Methods – Application Comparisons", Proceedings of Composites Durability Workshop-14 (CDW-14), UCLA, Jul, 2009

"Thermoelastic Shape Memory Modeling of Medical Devices with FEA", SMST-2006, The International Conference on Shape Memory and Superelastic Technologies, ASM International, May, 2006, (with Sanjay Choudhry and Jesse Lim).

"Finite Element and Fatigue Analysis of CardioVasc Stent Graft", CardioVasc, Inc., 2004.

"Analysis of Rail Cracking and Development of a Rail Screening Guideline Based on Fracture Mechanics Principles", Fatigue & Durability Assessment of Materials, Components & Structures, Proceedings of the Fifth International Conference of the Engineering Integrity Society, Queen's College, Cambridge, UK, Apr 7-9, 2003.

"Finite Element and Fatigue Analysis of CP Stent Expansion", NuMed, Inc., 2003.

"Evaluation of a Failure in a Chlorine Production Facility", Proceedings of IMECE 2001, ASME International Mechanical Engineering Congress and Exposition, Nov, 2001, New York, NY (with S. Andrew, R. Caligiuri, and L. Eiselstein).

"Physical Testing for Good Analysis: Experimental Validation for Quality Finite Element Analysis of Medical Devices", feature article for *ANSYS Solutions*, Fall 2000 (Machine Design Custom Media, Penton Media, Inc.).

"Finite Element Simulation of 180° Rollover for Heavy Truck Vehicles", ASCE Engineering Mechanics Conference, Baltimore, MD, Jun, 1999 (with Christopher V. White and Shari E. Day).

"Finite Element Analysis of the S670 Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1999.

"Finite Element Analysis of the S660 Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1999.

"Finite Element Analysis of the Six Crown Extra Support Renal Stent – Minimum Dimensions", Arterial Vascular Engineering, Inc., 1998.

"Finite Element Analysis of the SVG Stent", Arterial Vascular Engineering, Inc., 1998.

"Finite Element Analysis of the GFX-II Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1998.

"Analysis of Drill Pipe Joint Failures and Recommendations For Service", Failure Analysis Associates, Inc. Report, Nov, 1997 (with R.D. Caligiuri, L.E. Eiselstein, M. Wu, R. Huet).

"Finite Element Analysis of the GFX Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1997.

"Stress Analysis: AVE MicroStent-II Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1997.

"SAE Report CRP-12 Heavy Truck Crashworthiness – Phase II (180° Dynamic Rollover, Static Roof Crush Simulation)", SAE Headquarters, 1997.

"Heavy Truck 180º Dynamic Rollover and Static Roof Crush Simulation", Failure Analysis Associates, Inc. Report, Apr, 1996 (with C. White, S. Day, T. Khatua, and L. Cheng).

"Fracture Toughness by Small Punch Testing", *Journal of Testing and Evaluation*, Vol. 23(1), pp. 3-10, Jan, 1995 (with J. R. Foulds, P. J. Woytowitz and C. W. Jewett).

"Safety Analysis of Custom Designed Manufacturing Equipment", Proceedings, American Society of Mechanical Engineers Winter Annual Meeting, Safety Engineering and Risk Analysis, New Orleans, Louisiana, Nov, 1993, Vol. 1, pp. 111 (with G. L. Rao and R. D. Caligiuri).

"American Azide Corporation Reactor and Dryer Safety Studies", Failure Analysis Associates, Inc. Report, Jan, 1993 (with G. L. Rao, V. B. Rao, and R. D. Caligiuri).

"Combustion Tests on and Chemical Analysis of Therminol 66 Heat Transfer Fluid Used at American Azide", Failure Analysis Associates, Inc. Report, 1993 (with A. Reza and R. D. Caligiuri).

"Gas Release from Leaky Natural Gas Pipeline: The PEPCON Explosion in Henderson, Nevada", Failure Analysis Associates, Inc. Report, 1992 (with A. Reza, M. El-Fadel and R. D. Caligiuri).

"Computational Modeling of Dynamic Failure in Armor/Anti-Armor Materials", Failure Analysis Associates, Inc. Final Report to U.S. Army Research Office, Contract DAA-L03-88-C-0029, May, 1992.

"Analysis of Cracking in the Windsor Recovery Boiler Superheater", Failure Analysis Associates, Inc. Report to Domtar, Inc., Apr, 1992 (with R. D. Caligiuri, C. H. Lange and S. P. Andrew).

"Analysis of the Dynamic Response of a Buried Pipeline due to a Surface Explosion", *Computational Aspects of Impact and Penetration*, L.E. Schwer and R.F. Kulak, eds., Elme Press International, 1991 (with R. D. Caligiuri).

"Failure Analysis of Aerzen Screw Compressor Male Thrust Bearings", Failure Analysis Associates, Inc. Report to AECI Chlor-Alkali & Plastics, Ltd., Sep, 1991 (with C. C. Schoof).

"Gas Flow and Heat Transfer in a Pipe Tee Joint", Failure Analysis Associates, Inc. Report to Chevron Corporation, Nov, 1990 (with R. D. Caligiuri and A. Reza).

"Development of Dynamic Failure Criteria for Ceramic Armor Materials", Failure Criteria and Analysis in Dynamic Response Symposium, ASME Winter Annual Meeting, Nov, 1990, H.E. Lindberg, ed.

"DYNA3D Analysis of the Dynamic Response of a Buried Pipeline due to a Surface Explosion", DYNA3D User Group Conference, Bournemouth, Dorset, United Kingdom, Sep, 1990.

"Con Edison Hellgate Facilities Gas Main Rupture", Failure Analysis Associates, Inc. Report to Consolidated Edison Company of New York, Inc., Feb, 1990.

"Stress and Fracture Mechanics Analysis of Weld Cracking in a Rotary Ball Mill", American Society of Mechanical Engineers Winter Annual Meeting, Paper 89-WA/DE-17, San Francisco, California, Dec, 1989 (with C. A. Rau, Jr., H. F. Wachob and E. L. Kennedy).

"Analysis of the Plunger-to-Plunger Rod Joint in an Automotive Fuel Injector", Failure Analysis Associates, Inc. Report to Hitachi, Ltd., Oct, 1988 (with P. R. Johnston and B. Ross).

"Analysis of the Circumferential Seam Weld Cracking of Raw Grinding Mills", Failure Analysis Associates Report to Kaiser Cement Corporation, Nov, 1986 (with C.A. Rau, Jr., H.F. Wachob).

"Local Flexibility and Stresses in Cylindrical and Spherical Shells Due to External Loadings on Nozzles and Lug Attachments", A.F.I.A.P. Conference, Paris, France, Oct, 1986.

"Analysis of Piping Systems with Local Nozzle Flexibility Using Personal Computers", American Society of Mechanical Engineers Pressure Vessel and Piping Conference, New Orleans, LA, 1985.

"Numerical Improvement of Asymptotic Solutions and Nonlinear Shell Analysis", Ph.D. dissertation, Stanford University, Jun, 1984.

"Numerical Improvement of Asymptotic Solutions for Shells of Revolution with Application to Toroidal Shell Segments", *Computers & Structures*, Vol. 16, No. 1-4, 1982.

Consulting Projects - Selected

Client: NanoBio Genomics, Inc.
Project: Confidential

Client: Aquedeon Medical, Inc.
Project: Product development associated with implantable Nitinol medical device for aortic aneurysm; Duett product; Radial Stiffness Assessment; Correlate Test & Simulation

Client: Silver Spring Networks, Inc.; Ops A La Carte LLC
Project: Mechanical Accelerated Life Testing and Reliability Assessment of Commercial IoT Network-Connected Natural Gas Metering Equipment; Failure Analysis support; plastic component design, accelerated life testing; remote monitoring;

Client: F-Prime Capital Partners (former Fidelity Biosciences)
Project: Technical Due-Diligence review of prospective stealth-mode medical device investment

Client: SI-Bone, Inc.
Project: Design review of iFuse sacroiliac (SI) joint fixation devices; Competitive comparison

Client: TexasLDPC, Inc.
Project: Business Advisor; Flash Memory Technology development for error-correction; LDPC – Low-Density Parity Check; start-up

Client: Cerevatech Medical, Inc.
Project: Business Advisor; Medical Device developer of innovative Nitinol neurovascular stent and flow diverter devices, start-up

Client: Promed Medical Inc.
Project: Evaluation of deployment failure associated with Nitinol scaffold and bioabsorable PLGA cover material. Test protocols; assessment of data and development of strategy to increase device reliability.

Client: Topera Inc.
Project: Evaluation of Nitinol device failure in test and clinical setting used for 3D mapping associated with treatment of arrhythmia. Comparison of current design with proposed redesign.

Client: LC Therapeutics
Project: Assessment of Nitinol coronary device.

Client: CrossRoads Extremity Systems
Project: Design evaluation of Nitinol orthopedic devices for bone fixation with focus on foot & ankle devices including staples and plates; Report for 510K submission to FDA

Client: Bridgelux, Inc
Project: Design evaluation of LED Outdoor Lighting Module (OLM) for assembly and service conditions; assessment of polymeric, injection-molded components including FRP (fiber-reinforced plastic)

Client: Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Project: MEMs Patent Portfolio review and assessment

Client: Design Standards Corporation (DSC)
Project: Design analysis & report for injection-molded surgical ligation clip;

Client: Sirius Engineering LLC
Project: Nitinol Vena-Cava Filter; Implantable cardiovascular medical device

Client: Nitinol Technology, Inc.
Project: Design and assessment of large-scale nitinol components for seismic damping in civil structures (buildings, bridges, roadways); analysis & testing collaboration

Client: Varian Medical, Inc.
Project: Medical radiation oncology capital equipment; shipping hazard assessment

Client: Atsina Surgical LLC
Project: Injection molded surgical ligation clip; material testing; product design, development, and optimization

Client: Home Dialysis Plus
Project: Development of reliability & accelerated testing protocols for innovative dialysis system including mechanical, electronic, & software components

Client: Freedom Innovations, LLC
Project: Carbon Fiber Prosthetic Foot – failure analysis, simulation

Client: Ops A La Carte LLC
Project: Mechanical Design for Reliability classes; failure analysis; simulation of mechanical & thermal performance; accelerated testing and root-cause analysis; TTi Sunseeker solar tracker failure analysis, redesign after full system loss due to damage from high winds;

Client: OLT Solar
Project: Product improvement under high-temperature exposure

Client: VX Aerospace
Project: Composite material product design and validation

Client: Fidelity Biosciences
Project: Medical device due-diligence and technology evaluation pre-investment

Client: DJS Associates
Project: Automated food packaging equipment - failure analysis and assessment of root cause issues

Client: Tribal Engineering, LLC
Project: Various simulation and customer training projects

Client: Gerson Lehrman Group
Project: MEMs Sensors; Various other projects

Client: Ops A La Carte LLC
Project: Various Reliability Consulting projects; Mechanical Design for Reliability Training

Client: Revascular Therapeutics, Inc (acquired by Boston Scientific)
Project: Implantable medical device for treatment of calcified lesions

Client: City and County of San Francisco
Project: Glass failure; Trial prep

Client: Sagalio LLC
Project: Retractable screen for portable cellular devices

Client: New Energy Technologies, Inc
Project: Alternative Energy concept assessment & review

Client: Square One Medical
Project: Implantable medical device design, development, simulation

Client: Kyphon
Project: Device improvement for spinal interventional device

Client: ProMed, Inc
Project: Implantable medical device for spinal application

Client: Nuvation
Project: Instrumentation assessment

Client: Ovalis, Inc
Project: Nitinol PFO Closure Device development and design improvements

Client: Gateway Medical
Project: Vascular Closure Device

Client: Ensure Medical
Project: Vascular Closure Device

Client: Abbott Laboratories
Project: Continued development and cost reduction aspects for StarClose device.

Client: Integrated Vascular Solutions (IVS) (acquired by Abbot Labs)
Project: Design & development of StarClose nitinol closure device for arterial closure following interventional procedures. 2005 MDM Excellence Award

Client: Prolifix Medical
Project: Nitinol device to excise plaque buildup from arteries

Client: Coapt Systems
Project: Bioabsorbable devices for surgical and cosmetic procedures

Litigation Support Experience

Litigation Cases; Depositions & Expert Reports as Shown:

2022 to Present	Client:	Haley Guiliano LLP
	Case:	*Surgical Instrument Service Company, Inc. v Intuitive Surgical, Inc.*, Case No. , United States District Court, Northern District of California
	Project:	Anti-Trust case associated with EndoWrist devices for Da Vinci surgical robots. Engineering evaluation of repaired devices.
	Status:	
2022 to Present	Client:	Spector Roseman & Kodroff, P.C.
	Case:	*RE: Da Vinci Surgical Robot Antitrust Litigation*, Lead Case No. 3:21-cv-03825-vc, United States District Court, Northern District of California
	Project:	Anti-Trust case associated with EndoWrist devices for Da Vinci surgical robots. Engineering evaluation of repaired devices.
	Status:	
2022	Client:	Calfee, Halter & Griswold, LLP
	Case:	*LG Electronics, Inc v. Multiple Respondents,* Certain Refrigerator Water Filtration Devices and Components Thereof, Investigation No. 337-TA-1290, United States International Trade Commission (ITC), Washington, D.C.
	Project:	ITC Investigation regarding alleged Validity and Infringement of 3 LGE patents for Refrigerator Water Filtration technology.
	Status:	Settled; Invalidity & Non-Infringement Declarations, June 2022. Deposition, July 2022.
2021 to 2022	Client	Banner Witcoff
	Case:	*Aspen Medical Products, LLC v Breg Inc.*Case No.3:21-cv-00631-WQH-MDD in the United States District Court, Southern District of California
	Project:	Patent matter regarding medical body and cervical support braces
	Status:	Settled.
2021 to 2022	Client:	Dovel & Luner, LLP
	Case:	*Rebotix Repair LLC v Intuitive Surgical, Inc.,* Case No. 8:2020cv02274, United States District Court, Middle District of Florida, Tampa Division.
	Project:	Anti-Trust case associated with EndoWrist devices for Da Vinci surgical robots. Engineering evaluation of repaired devices.
	Status:	Settled; Expert Report, Aug 2021; Deposition, Sep 2021;
2021 to 2022	Client	Gibson, Dunn & Crutcher, LLP
	Case:	Confidential Case – United States District Court, Central District of California.
	Project:	Patent matter associated with beverage systems and components
	Status:	Settled.

2021	Client:	Schlichter & Shonack, LLP
	Case:	*KV Inc v Heartstitch, Inc.,* Case No. 30-2019-01051080-CU-BC-NJC in the Superior Court for the State of California, County of Orange
	Project:	Assessment of FDA regulated custom manufactured medical device components for heart surgery. Assessment of conformance and quality.
	Status:	Settled
2021	Client:	Dentons, London, UK
	Case:	Confidential Case - *European Patent Office review*
	Project:	Medical device patent; Support review process
	Status:	European Patent Office (EPO) Declaration 2021;
2021 to Present	Client:	Rosen & Perry, P.C.
	Case:	*Chamber v. Dollar Tree Store, et.al.;* Case No. , Superior Court, Pennsylvania
	Project:	Personal Injury, warnings, device evaluation; – material and load evaluation of hair device; tissue damage due to pressure
	Status:	Ongoing.
2021 to Present	Client:	Cogan & Power, PC
	Case:	*Michele Volk v. Stryker Medical, et.al*
	Project:	Investigate microcatheter failure during medical procedure.
	Status:	Ongoing.
2021	Client:	Thompson Coburn LLP
	Case:	*Widdenmeyer v. Zoll Medical, Ranken-Jordan Hospital, et.al.* Case No. , Superior Court, St.Louis, MO
	Project:	Investigate alleged malfunction and defect in AED (Automated External Defibrillator). Site inspection.
	Status:	Resolved
2020 to Present	Client:	Klarquist Sparkman, LLP
	Case:	Various - Patent
	Project:	Medical device patent
	Status:	Ongoing.
2020	Client	Morrison & Foerster, LLP on behalf of Apple, Inc.
	Case:	In RE: Macbook Keyboard Litigation; Various Plaintiffs, vs. Apple Inc.; Case No. 5:18-CV-02813-EJD-VKD United States District Court Northern District of California, San Jose Division
	Project:	Potential Class Action and Class Certification; Laptop Keyboard technology; design, performance, repair rates.
	Status:	Expert Report, Sep 2020; Deposition, Oct 2020;

2020	Client:	Baker & Hostetler, LLP
	Case:	*NEXTracker vs. Solar FlexRack and Northern States Metals Co.,* United States District Court, District of Delaware
	Project:	Patents; Solar tracker technology patents associated with Guide Rails, Clamps, etc.
	Status:	Settled; IPR Declaration Oct 2020;
2020 to 2021	Client:	Merchant & Gould P.C.
	Case:	*Otter Products, LLC and Treefrog Developments, Inc. vs Fellowes, Inc.* United States District Court, Northern District of Illinois, Eastern Division;
	Project:	Patents; Consumer Electronics technology for protection of personal electronics (cell phones, tablets, etc.) against drop, moisture, etc.
	Status:	Settled; IPR Declarations: 2-Aug 2020; 2-Dec 2020; 1-Jan 2021; Patent Infringement;
2020 to 2022	Client:	Bienert Katzman PC
	Case:	*Julie Hall, vs. Torax Medical, Inc., Ethicon, Inc., Johnson & Johnson, John Lipham, MD, et.al,* Case No. 30-2019-01078281-CU-PL-CJC in the Superior Court for the State of California, County of Orange
	Project:	Personal injury, product liability associated with medical device to treat Gastric Reflux Disease (GERD)
	Status:	Settled
2020 to Present	Client:	The Cottle Firm
	Case:	*Richard vs. American Honda Motor Co., Inc., Home Depot USA, Inc., et.al.* Case No. A-19-791675-C in the Nevada State District Court, Clark County, Nevada
	Project:	Personal injury, product liability associated with rototiller
	Status:	Deposition Nov 2021; Expert Report May 2020, Aug 2021; Ongoing.
2020 to Present	Client:	Todd Tracy Law Firm
	Case:	*Hendricks v DTNA, Freightliner. et.al*; Cause No. 103610-86 in the District Court, Kaufman County, TX, 86th Judicial District
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Ongoing.
2020	Client:	Todd Tracy Law Firm
	Case:	*Guerra v Navistar*; Case No. 1:18-CV-00321-KG-JFR, United States District Court for the District of New Mexico
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Deposition, Aug 2020; Settled

2019 to 2020	Client:	Singer Davis LLC
	Case:	*McIntosh vs. EVMS Academic Physicians & Surgeons Health Services Foundation, Covidien Holding, Inc., Cook Medical, LLC, et.al.* Case No. CL18-4817 in the Circuit Court for the City of Norfolk Virginia
	Project:	Personal Injury, Product Liability related to Percutaneous Tracheostomy Tube;
	Status:	Settled
2019	Client:	Venable LLP
	Case:	*Disc Disease Solutions, Inc., vs. VGH Solutions, Inc. Dr-Ho's Inc., Hoi Ming Michael Ho.* Case No. 1:15-cv-00188-LJA, United States District Court, Middle District of Georgia, Albany Division
	Project:	Patents; Medical Device, Back-Pain Relief;
	Status:	Settled; Claim construction, invalidity, non-infringement; Claim construction Declaration Aug 2019;
2019	Client:	Baker & Hostetler, LLP
	Case:	*Zadro Products, Inc. vs. SDI Technologies, Inc. d/b/a iHOME.* Case No. 17-1406 (WCB) in the United States District Court for the District of Delaware
	Project:	Patents; Consumer products, LED lighting, mirrors
	Status:	Settled
2019	Client:	Gardella Grace P.A.
	Case:	*Fulfillium, Inc. vs. ReShape Medical, LLC, SV Health Investors, LLC, Intersect Partners, LLC and ReShape Lifesciences, Inc.* Case No. 8:18-cv-01265-RGK-PLA United States District Court, Central District of California, Western Division
	Project:	Patents; medical devices, balloons, weight control
	Status:	Settled; Deposition Aug 2019; Expert Report Aug 2019; Declaration on Motion for Summary Judgement Aug 2019;
2019	Client:	Merchant & Gould
	Case:	*Carlson Pet Products, Inc. v. North States Industries, Inc..* Case No. 17-cv-02529- PJS-KMM, United States District Court for the District of Minnesota
	Project:	Patents, Consumer product; Pet barrier
	Status:	Settled; Declaration, Oct 2019;
2019 to Present	Client:	Todd Tracy Law Firm
	Case:	Multiple cases
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Ongoing.

2019	Client:	Sterne, Kessler, Goldstein & Fox, P.L.L.C. (SKGF)
	Case:	*Lutron v. Geigtech*
	Project:	Patent Post-Grant Review (PGR); Other PTAB actions
	Status:	Suspended
2019 to Present	Client:	Faegre Baker Daniels LLP
	Case:	Confidential MDL Product Litigation
	Project:	Confidential
	Status:	
2019 to 2022	Client:	Rouda Feder Tietjen McGuinn
	Case:	*Margo Schein v. Peak Pilates*
	Project:	Inspection of Pilates Reformer equipment; Accidental injury root-cause assessment; explain accident scenarios; Support for mediation;
	Status:	Resolved;
2019	Client:	Manning & Kass, Ellrod, Ramirez, Trester LLP
	Case:	*Randy and Giselle Hoehn v. Summit to Sea LLC, Pet Pressure LLC.*
	Project:	Hyperbaric pressure chamber inspection, operation, and design review. Accidental injury investigation.
	Status:	Settled
2018 to 2020	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Miriam Naramore v. Daimler Trucks North America, LLC.* Civil Action No. 1:18-CV-00156 in United States District Court for the Middle District of Georgia, Albany Division.
	Project:	Heavy-truck rollover & crashworthiness; design assessment
	Status:	Settled
2018 to 2021	Client:	Maddin, Hauser, Roth & Heller, P.C.
	Case:	*Larry Esckilsen and Renie Esckilsen v. Oakland Orthopedic Appliances, Inc.;* Case No. 18-036354-NO-1 Saginaw Circuit Court
	Project:	Alleged failure of orthopedic leg prosthetic; personal injury
	Status:	Settled; Deposition, Sep 2020;
2018 to 2019	Client:	Klein, DeNatale, Goldner, LLP
	Case:	*H&M Gopher Control, Allen Hurlburt v. Benchmark Pest Control, Inc., Andrew Ozanich.* Case No. 1:17-CV-01700-JLT, United States District Court for the Eastern District of California
	Project:	Patent technology for control of rodents
	Status:	Settleld; Expert Report, Jan 2019;
2018 to 2019	Client:	Cypress LLP
	Case:	*Kore Essential, Inc v. Nexbelt, LLC.* Case No. 3:17-CV-02129-CAB-JMA, United States District Court for the Southern District of California
	Project:	Patent technology for Ratchet Belt system
	Status:	Settled; Expert Report, Feb 2019;

2018 to 2019	Client:	Pillsbury Winthrop Shaw Pittman, LLP
	Case:	*Lite-On Technology Corp v Darfon Electronics Corp,* Case No. 3:18-cv-02776, United States District Court, Northern District of California.
	Project:	Keyboard technology patents
	Status:	Settled; IPR Declaration Dec 2018;
2018 to 2020	Client:	Honigman Miller Schwartz & Cohn LLP
	Case:	*Tim A. Fischell, Robert E. Fischell, and David R. Fischell v. Cordis Corp, Abbott Laboratories and Abbott Cardiovascular Systems, Inc.*, United States District Court for the District of New Jersey; Civil Action No. 3:16-cv-00928-PGS-LHG
	Project:	Patent family associated with cardiovascular stents
	Status:	Settled; Declaration, Apr 2019;
2018	Client:	Akerman, LLP
	Case:	*Qbex Computadores S.A v. Intel Corporation,* United States District Court, Northern District of California, San Jose Division.
	Project:	Cellular phone ARM microprocessor, alleged product design defect associated with CPU overheating
	Status:	Settled
2018 to 2019	Client:	Davidson, Davidson & Kappel LLC
	Case:	ArcelorMittal Project; *Inter Partes Review Proceeding Against Array Technologies Inc. U.S. Patent 8,459,249*
	Project:	Patent IPR associated with solar panel trackers
	Status:	Settled; Deposition Dec 2018; IPR Declaration Mar 2018;
2018 to 2019	Client:	Ropes & Gray LLP
	Case:	*CPI Card Group, Inc. v. Multi-Packaging Solutions, Inc* , United States District Court for the District of Colorado
	Project:	Patent associated with secure packaging of transaction/gift cards; Testing
	Status:	Resolved
2017 to 2018	Client:	Rimon Law
	Case:	*Imogene D. Johns v. Invacare Corporation,* Tulare County Superior Court Case No. 270201
	Project:	Alleged medical equipment product defect
	Status:	Settled
2017 to 2018	Client:	The Scranton Law Firm
	Case:	*Cesar Lopez & Moses Sepulveda v. DOES-1*
	Project:	Alleged design defect in ATV Rollover Protection System (RoPS); Design and Failure Analysis
	Status:	Resolved;

2017 to 2018	Client:	Troutman Sanders LLP; Vinson & Elkins
	Case:	*Blackbird Tech LLC d/b/a Blackbird Technologies v. Lenovo (United States) Inc.;,* C.A. No. 16-cv-140-RGA, United States District Court for the District of Delaware
	Project:	Patent infringement allegations around laptop computer screen display technology
	Status:	Settled; Declaration May 2018; Deposition Feb 2018; Reply Report Dec 2017; Non-Infringement Report Nov 2017; Invalidity Report Sep 2017;
2017	Client:	White & Case LLP
	Case:	*Maquet Cardiovascular LLC v. Abiomed Europe GmbH and Abiomed R&D, Inc.*; C.A. No. 1:16-CV-10914, United States District Court for the District of Massachusetts
	Project:	Resolved; Multiple Patent & Technology dispute associated with Implantable Circulatory Support System Pumps
2017 to 2018	Client:	Baker & Hostetler, LLP
	Case:	*SCA Hygiene Products AB et.al., SCA Tissue North America, LLC v. Tarzana Enterprises, LLC;* United States District Court, Western District of Wisconsin, No. 3:16-cv-00728
	Project:	Patent infringement claims associated with paper goods manufacturing, stacking, folding, and packaging methods and equipment
	Status:	Settled; Depositions (2) Sep 2018; IPR Response Declarations, Jul 2018 (2), May 2018;
2017	Client:	Vinson & Elkins
	Case:	*Inter Partes* Review of U.S. Patent No. 7,129,931; *Lenovo (United States) Inc. v. Blackbird Tech LLC d/b/a Blackbird Technologies; Blackbird Technology LLC v. Lenovo, Civil Action No. 1:16-cv-00140 in the District of Delaware*
	Project:	Patent IPR and alleged infringement involving laptop computer display apparatus
	Status:	Deposition Feb 2018; Expert Report; IPR Declaration May 2017;
2017 to Present	Client:	The Joe C. Savage Law Firm
	Case:	*Bauer v. Parks, Hyundai Motors America, and Deskins Motor Company and other related cases;*
	Project:	Vehicle Accident Investigation, Design, Crashworthiness, Fire
	Status:	Settled

2017 to 2018	Client:	Hill, Kertscher & Wharton, LLP
	Case:	*Trans Technologies Company v. Hendrickson USA LLC, et.al.*, United States District Court for the Northern District of Georgia, Atlanta Division, Civil Action No. 1:16-cv-01778-AT
	Project:	Patent litigation involving heavy-truck tire inflation/deflation technology
	Status:	Settled; Deposition Jul 2018; Deposition Apr 2018; IPR Declaration Aug 2017; IPR Reply Declaration Feb 2018;
2017 to 2018	Client:	Morgan, Lewis & Bockius LLP
	Case:	*Advanced Circulatory Systems, Inc. v. AutoMedx, Inc.,* and *AutoMedx, Inc v. ZOLL Medical Corp., Advanced Circulatory Systems, Inc.;* CPR Institute for Dispute Resolution, CPR File No. G-16-07
	Project:	Medical Ventilator Technology Development; Medical equipment
	Status:	Settled
2017	Client:	Dorsey & Whitney LLP
	Case:	*Hovik Nazaryan v. FemtoMetrix Inc.*, Superior Court of the State of California for the County of Orange Case No. 34-30- -2015-00795246-CU-BC-CJC
	Project:	Semiconductor lithography equipment technology development
	Status:	Settled
2016 to Present	Client:	Casper, Meadows, Schwartz & Cook
	Case:	*Rovner v. Medtronic, Inc. et.al.* Contra Costa Superior Court, Case No. C16-01768
	Project:	Medical Device defect of NSC spinal lumboperitoneal (LP) Shunt/Valve for hydrocephalus shunting of excess cerebrospinal fluid (CSF); associated personal injury
	Status:	Settled
2016 to 2018	Client:	Rimon Law
	Case:	*Heather Ciechanowski v. Invacare Corporation, Folsom Care Center, Bluff Enterprises, Inc. and Calvin Callaway*, Sacramento County Superior Court Case No. 34-2016-00188724
	Project:	Alleged medical equipment product defect
	Status:	Settled
2016 to 2017	Client:	Rucka, O'Boyle, Lombardo & McKenna
	Case:	*Concepcion Hernandez v. Helen of Troy, Inc;*
	Project:	Medical equipment personal injury
	Status:	Settled

2016 to 2017	Client:	Quinn Emanuel Urquhart & Sullivan, LLP
	Case:	*TriReme Medical LLC v. AngioScore, Inc.*, Northern District of California; Case No. 14-cv-2946
	Project:	Patent litigation involving cardiovascular medical device
	Status:	Deposition, Dec.2016; Expert Reports, Nov.2016 & Dec.2016; Settled
2016 to 2017	Client:	Baker Manock & Jensen, PC
	Case:	*California Fire-Roasted LLC v. General Mills Operations, LLC;* Sacramento County Superior Court Case No. 34-2014-00170784-CU-BC-GDS
	Project:	Patent licensing and royalty case for food-processing equipment
	Status:	Settled
2016 to 2017	Client:	DLA Piper, LLP
	Case:	*Inter Partes* Review of U.S. Patent No. 6,099,882; *Olam West Coast, Inc. v. California Fire-Roasted LLC*
	Project:	Patent IPR involving food-processing equipment
	Status:	Settled; IPR Declarations (2) Oct.2016;
2016 to 2018	Client:	Plews Shadley Racher & Braun, LLP; Bradshaw Law, LLC
	Case:	*Rick C. Sasso, M.D., and SEE LLC v. Warsaw Orthopedic, Inc., Medtronic Inc., Medtronic Sofamor Danek, Inc*, Indiana State Court, Case No. 43C01-1308-PL-44.
	Project:	Patent litigation involving coverage for spinal medical device
	Status:	Deposition Aug 2018; **Patent Trial Testimony Nov 2018**; Jury Verdict for Plaintiff; Upheld on Appeal Dec 2020;
2016 to Present	Client:	Christensen Fonder, P.A.
	Case:	*Willis Electric Co., Ltd v. Polygroup Limited (Macao Commercial Offshore), Polygroup Macau Limited (BVI), Polytree (H.K.) Co. Ltd.,* 15-cv-3443, 3:15-cv-00552, United States District Court for the District of Minnesota.
	Project:	Patent litigation involving modular mechanical and electrical connectors
	Status:	Settled
2016 to Present	Client:	Locke Lord LLP
	Case	*Denneroll Holdings Pty Limited and Denneroll Industries International Pty Limited v. ChiroDesign Group, LLC and Marie L. Webster, Individually and D/B/A ChiroDesign Group;* Civil Action No. 4:15-cv-740; United States District Court for the Southern District of, Houston Division.
	Project:	Patent litigation involving chiropractic pillows
	Status:	Settled; Infringement Expert Report, May 2016; Validity Expert Report, June 2016

2016 to Present	Client:	Mass Montes LLP
	Case:	*Logan W. Hensley vs. Michael J. Skyhar, MD.; Cayenne Medical, Inc., and DOES 1 thru 40, inclusive;* Case no. 37-2015-00005140-CU-MM-NC, Superior Court for the State of California for the County of San Diego, North County Division.
	Project:	Personal injury involving failed medical device and medical practice
	Status:	Settled
2016 to Present	Client:	Hamrick & Evans, LLP
	Case:	*Laurence Johnson vs. Raytheon Company, Systems XT, Inc. Brownco Construction Company, Inc., Power Edge Solutions, Inc. (aka PES Controls), et.al.* United States District Court for the Central District of California; Case No. 2:15-cv-00132-MWF-E.
	Project:	Personal Injury; Product Performance & Product Liability
	Status:	Settled
2015 to 2016	Client:	Nixon Peabody LLP
	Case:	*Johnstech International Corp v. JF Microtechnology SDN BHD* United States District Court for the Northern District of California; Case No. 3:14-cv-02864-JD
	Project:	Patent litigation involving semiconductor test technology
	Status:	Invalidity Expert Report, Non-Infringement Expert Report – Dec 2015; **Patent Trial Testimony – Sep 2016**. Jury Verdict.
2015	Client:	Susman Godfrey LLP
	Case:	*Bonutti Skeletal Innovations, LLC v. Globus Medical, Inc*
	Project:	Patent litigation involving spinal medical devices
	Status:	Settled
2015	Client:	Richardson, Patrick, Westbrook, & Brickman, LLC
	Case:	*Smart v. PACCAR*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled
2014 to 2018	Client:	Harris and Graves, P.A.
	Case:	*Raven N. Dineen v. Sprint Corp, Asurion Protection Services, LLC and Apple, Inc.,* District Court, Greenville Division, District of South Carolina, No. 6:16-cv-01549-MGL
	Project:	Investigation of alleged cellular telephone defect and Lithium-Ion battery breach; Personal injury (victim sustained burns) due to ignition & combustion of cell phone; Non-Destructive & Destructive Inspections
	Status:	Settled; Deposition Oct 2017; Expert Report, July 2015, July 2017;

2014 to 2019	Client:	Law Offices of David McQuade Leibowitz, P.C.
	Case:	*Ricardo Garza v. Daimler Truck of North America (DTNA), Freightliner LLC;* Texas Circuit Court, Bexar County, Texas
	Project:	Heavy Truck Crashworthiness
	Status:	Trial Testimony Sep 2019; Deposition Jul 2018; Expert Report Apr 2018; Jury Verdict;
2014	Client:	Kolisch Hartwell, P.C.
	Case:	*TMI Products, Inc. v. Rosen Entertainment Systems, L.P* United States District Court for the Central District of California; Case No. EDCV12-02263 RGK (SPx)
	Project:	Patent case involving consumer electronics & vehicle entertainment applications
	Status:	Settled; Deposition March 2014; Declaration & Report March 2014; Declaration & Rebuttal Report March 2014;
2014 to 2018	Client:	Corsiglia, McMahon, & Allard
	Case:	*Avalos v. Balt, Stanford Hospital & Clinics, et.al.*
	Project:	Personal Injury during Medical Procedure & Medical Device Product Liability; Failure analysis of micro-catheter for neurovascular treatment; embolization of a cerebral AVM during procedure at Stanford Hospital
	Status:	Settled
2014 to 2015	Client:	The Previant Law Firm, S.C.
	Case:	*Kaminski v. DongGuan, et.al.*
	Project:	Personal injury (eye damage) due to failure of consumer product (elastomeric strap tie-down); Failure analysis, material testing, and evaluation of elastomeric material components
	Status:	Settled; Expert Report, July 2014
2013 to 2015	Client:	Guajardo & Marks, LLP
	Case:	*Bertha A. Flores Individually and as Representative of the Estate of Jose Flores, et.al. v Daimler Trucks North America, LLC.* United States District Court for the Southern District of Texas, Corpus Christi Division, and is Civil Action No. 2:13-cv-87
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled, Mar 2015 Deposition, Feb 2015; Report, Oct 2014
2012 to 2014	Client:	Edwards Life Sciences; Kilpatrick, Townsend & Stockton, LLP
	Case:	*Medtronic v. Edwards* Case No. 11-CV-1650-JNE/JSM (D. Minn.)
	Project:	Medical device patent claims, infringement & invalidity
	Status:	Settled Invalidity Report Aug 2013; Non-Infringement Report Oct 2013; Deposition Oct 2013, Oct 2012

2013 to 2014	Client:	US Securities and Exchange Commission
	Case:	*Securities and Exchange Commission (SEC) v. Inteligentry, Ltd., Plasmerg, Inc., PTP Licensing, Ltd., and John P. Rohner in Civil No. 2:13-CV-00344-GMN-NJK*
	Project	Securities associated with "Plasmic Transition Process Engine" technology; Technology assessment
	Status:	Resolved
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Walker v. PACCAR, Inc;* Alabama Circuit Court, Barbour County; 06-CV-2013-900032.00
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled
2013	Client:	Retained in a metal component manufacturing technology patent litigation case.
	Case:	*Confidential*
	Project:	Metal manufacturing process patent for smart-phone and consumer electronics applications
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Lacy v. Freightliner*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled Mar 2015
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Jones vs. Daimler Truck North America (DTNA)* Alabama Circuit Court
	Project:	Heavy Truck Rollover & Crashworthiness
	Status:	Settled Nov 2015; Deposition Jan 2014
2012	Client:	Smart-phone technology patent litigation case involving embedded electro-mechanical components
	Case:	*Confidential*
	Project:	Patent issues associated with specific user-feedback technologies
	Status:	
2010 to 2015	Client:	Warren & Associates, LLC
	Case:	*Jones vs. MSE Hauling*
	Project:	Heavy Truck Rollover
	Status:	Settled Nov 2015; Deposition Jan 2014
2009 to 2014	Client:	Schwarz & Mongeluzzi; Nelson, Levine, DeLuca & Horst
	Case:	*Carrera v. Navistar*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled 2014; Deposition Feb 2013

2010	Client:	Sico, White, Hoelscher & Braugh L.L.P.
	Case:	*Ramirez v. Sterling Truck*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled; Expert Report; Deposition May 2010
2008 to 2010	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Thibadeaux vs. PACCAR*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2010.
2008 to 2010	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Price vs. Navistar*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2010.
2008 to 2009	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Martin vs. Kenworth*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2009.
2007	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Strode v. Freightliner, LLC;* Civil Action No. 02-132 Circuit Court of Greene County Alabama
	Project:	Heavy-Truck Rollover Accident
	Status:	Settled; 2007. Testified at trial.
2006	Client:	Gibson, Dunn, & Crutcher
	Case:	*Jang v. Boston Scientific Corp., et.al.* United States District Court, Central District of California; Eastern Division – Riverside; Case No: EDCV 05-00426 VAP (SGLx)
	Project:	Patent case for matters involving design features of Cardiovascular Stents.
	Status:	
2005	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Mongan vs. MACK Truck*
	Project:	Retained as fact witness in heavy truck rollover accident.
	Status:	Settled, 2005
2005	Client:	Lucas Wash Petway Tucker & Stephens, P.C.
	Case:	*Gable v. International Truck & Engine Corporation* United States District Court, Middle District of Pennsylvania; Civil Action No: 3:03-CV-01353
	Project:	Heavy-Truck Rollover Accident
	Status:	Closed; Deposition June 2005.

2004	Client:	Kenyon & Kenyon Intellectual Property Law Firm
	Case:	*Medtronic Vascular, Inc. vs. Boston Scientific Corp., et al.* C.A. No. 98-478-SLR (D-Del)
	Project:	Patent case involving Cardiovascular Stent design
	Status:	Closed; Expert Report filed;
1997	Client:	Grimaldi, Pearson,and Weyand, P.C.
	Case:	*Herbolsheimer v. Warner-Swasey* Case No. 9357487NP
	Project:	Product defect of CNC machine equipment
	Status:	Closed; Deposition.
1994	Client:	Jones, Jones, Close & Brown
	Case:	*Pioneer Chlor-Alkali Co., Inc. v. National Union Fire Insurance Co.*, United States District Court, District of Nevada, Case No. CV-S-93-276-HDM (RLH)
	Project:	Accident investigation, insurance claim.
	Status:	Closed; Deposition.
1994	Client:	Clapp, Moroney, Bellagamba, Davis and Vucinich
	Case:	*Thomas Fujisaka and Sandra Fujisaka v. Livermore Valley Unified School District*, Superior Court of the State of California In and For the County of Alameda, Case No. 700921-1
	Project:	Accident Investigation, Personal Injury
	Status:	Closed; Deposition.
1994	Client:	GEA In-House Counsel
	Case	*GEA Power Cooling Systems, Inc. v. Hyspan Precision Products*, Superior Court of the State of California for the County of San Diego, Case No. 669769
	Project:	Product Liability; Failure analysis root cause.
	Status:	Closed; Deposition.
1993	Case	*Bobbye J. Phaneuf v. Edith D. Roman*, Superior Court of the State of California County of Alameda, Case No. H - 154330-4
	Project:	Product Design.
	Status:	Closed; Deposition, Trial.
1993	Case:	*Patricia C. Barbera v. H. B. Instrument Company*, Superior Court of the State of California In and For the County of Marin, Case No. 138929
	Project:	Product Design.
	Status:	Closed; Deposition, Trial.

1990	Client:	Chevron In-House Counsel
	Case:	*Secretary of Labor v. Chevron U.S.A, et al.*, Occupational Safety and Health Review Commission, Region 9, OSHRC Docket No. 89-3125
	Project:	Accident investigation; Failure analysis root cause.
	Status:	Closed; Deposition.

Trials & IPRs:

2020	Case:	*NEXTracker vs. Solar FlexRack and Northern States Metals Co.,*. United States District Court, District of Delaware
	Status:	IPR Declaration Oct 2020;
2020	Case:	*Otter Products, LLC and Treefrog Developments, Inc. vs Fellowes, Inc.* United States District Court, Northern District of Illinois, Eastern Division.
	Status:	IPR Declarations 2-Aug 2020; 2-Dec 2020; 1-Jan 2021;
2019	Case:	*Ricardo Garza v. Daimler Truck of North America (DTNA), Freightliner LLC;* Texas Circuit Court, Bexar County, Texas
	Status:	Testified in Trial, Sep 2019
2018	Case:	*Lite-On Technology Corp v Darfon Electronics Corp,* Case No. 3:18-cv-02776, United States District Court, Northern District of California.
	Status:	IPR Declaration Dec 2018;
2018	Case:	*Rick C. Sasso, M.D., and See LLC v. Warsaw Orthopedic, Inc., Medtronic Inc., Medtronic Sofamor Danek, Inc*, Indiana State Court, Case No. 43C01-1308-PL-44.
	Status:	Testified in Patent Trial, Nov 2018
2018	Case:	*SCA Hygiene Products AB et.al., SCA Tissue North America, LLC v. Tarzana Enterprises, LLC;* United States District Court, Western District of Wisconsin, No. 3:16-cv-00728
	Status:	IPR Response Declarations, July 2018 (2), May 2018;
2018	Case:	Davidson, Davidson & Kappel LLC; ArcelorMittal Project
	Status:	IPR Declaration, Mar 2018;
2017	Case:	*Trans Technologies Company v. Hendrickson USA LLC, et.al.*, United States District Court for the Northern District of Georgia, Atlanta Division, Civil Action No. 1:16-cv-01778-AT
	Status:	IPR Declaration Aug 2017; IPR Response Declaration Feb 2018;

2017	Case:	*Lenovo (United States) Inc. v. Blackbird Tech d/b/a Blackbird Technologies*, Review of U.S. Patent No. 7,129,931;
	Status:	Deposition Feb 2018; Expert Report; IPR Declaration May 2017;
2016	Case:	*Olam West Coast, Inc. v. California Fire-Roasted LLC; Inter Partes* Review of U.S. Patent No. 6,099,882
	Status:	IPR Declarations (2), Oct 2016;
2016	Case:	*Johnstech International Corp. v. JF Microtechnology SDN BHD;* Action 14-cv-02864-JD, US Federal Court, District of Northern California
	Status:	Testified in Patent Trial, Sep 2016
2007	Case:	*Strode v. Freightliner, LLC;* Civil Action No. 02-132 Circuit Court of Greene County Alabama
	Status	Testified in Product Liability/Personal Injury case;
1995	Case:	*Bobbye J. Phaneuf v. Edith D. Roman*; Superior Court of the State of California County of Alameda, Case No. H-154330-4
	Status:	Testified in Product Liability/Personal Injury case;
1994	Case:	*Patricia C. Barbera v. H. B. Instrument Company*; Superior Court of the State of California In and For the County of Marin, Case No. 138929
	Status:	Testified in Product Liability case;

ATTACHMENT B

Materials Considered

Materials Considered

- "303 Stainless Steel." Penn Stainless, 5 Dec. 2018, www.pennstainless.com/resources/product-information/stainless-grades/300-series/303-stainless-steel/.
- "Access and instruments product catalog" Medtronic, 2020, available at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf.
- "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik.html.,
- Anderson, Patrick L., et al. "Robot-like Dexterity without Computers and Motors: a Review of Hand-Held Laparoscopic Instruments with Wrist-like Tip Articulation." Expert Review of Medical Devices, vol. 13, no. 7, 2016, pp. 661–672., doi:10.1586/17434440.2016.1146585., at page
- "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf
- "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/
- "Flex Robotic System Technology: How it Works," available at: https://medrobotics.com/gateway/technology/
- "Flexible 'open architecture' instrumentation," available at: https://medrobotics.com/gateway/instruments/
- "Tungsten." *Elmet Technologies*, www.elmettechnologies.com/tungsten/.
- Center for Devices and Radiological Health. "A History of Medical Device Regulation and Oversight in the US." *U.S. Food and Drug Administration*, FDA, www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states.
- Center for Devices and Radiological Health. "Current Good Manufacturing Practice Final Rule; Quality System." *U.S. Food and Drug Administration*, FDA, www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation.
- Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff, issued on October 25, 2017
- Koukourikis P, Rha KH. Robotic surgical systems in urology: What is currently available? Investigative and Clinical Urology. 2021
- Design Control Guidance for medical Device Manufacturers, US Food and Drug Administration, https://www.fda.gov/media/116573/download

- DS2505 Dallas Semiconductor data sheet, available at: https://datasheets.maximintegrated.com/en/ds/DS2505.pdf
- Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administrative Staff, issued on June 18, 2021
- Richard G. Budynas and J. Keith Nisbett, Shigley's Mechanical Engineering Design, Ninth Edition, McGraw-Hill, New York, 2008
- Ruurda, Jelle P., et al. "Analysis of Procedure Time in Robot-Assisted Surgery: Comparative Study in Laparoscopic Cholecystectomy." Computer Aided Surgery, vol. 8, no. 1, 2003, pp. 24–29., doi:10.3109/10929080309146099.
- Safe Medical Devices Act of 1990
- Scheer, Adena, et al. "Laparoscopic Colon Surgery: Does Operative Time Matter?" Diseases of the Colon & Rectum, vol. 52, no. 10, 2009, pp. 1746–1752., doi:10.1007/dcr.0b013e3181b55616.
- Senhance Surgical System EMEA Product Catalog, January 2020
- Senhance.com/indications
- Shigley's Wire Rope Chapter
- Shushan A, Mohamed H, Magos AL. How long does laparoscopic surgery really take? Lessons learned from 1000 operative laparoscopies. Hum Reprod. 1999 Jan;14(1):39-43. doi: 10.1093/humrep/14.1.39. PMID: 10374091.
- Steel, Alro. "303 Stainless Steel." 303 Stainless Steel | Chromium-Nickel Stainless Steel | Alro Steel, www.alro.com/divsteel/metals_gridpt.aspx?gp=0117
- U.S. Navy Wire-Rope Handbook, Vol. 1
- Urology-robot-compare-icu-62-14
- Medical Device Amendments of 1976
- Medical Device Reporting for Manufacturers – Guidance for Industry and Food and Drug Administration Staff
- Medtronic-access-instrumentation-products-catalog
- Premarket Notification 510(k)
- Rebotix Complaint (ECF No. 1)
- Complaint, Surgical Instruments Service Co., Inc. v. Intuitive Surgical, Inc., Case No. 3:21-CV-03496-VC (N.D. Cal.)
- Rebotix's Supplemental Responses and Objections to Intuitive's First Set of Interrogatories
- Intuitive's Answer, Affirmative Defenses and Counterclaims (ECF No. 49)
- FDA website provides a description of MAUDE: https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude
- Fiegel Conversation
- Greg Posdal Conversation
- 2001 Intuitive 10-K

- June 15th, 2021, Deposition of Bob Overmars (with accompanying exhibits)
- June 22nd, 2021, Deposition of Chris Gibson (with accompanying exhibits)
- June 2nd, 2021, Deposition of Glenn Papit (with accompanying exhibits)
- June 4th, 2021, Deposition of Mark Johnson (with accompanying exhibits)
- June 7th, 2021, Deposition of Anthony McGrogan (with accompanying exhibits)
- May 14th, 2021, Deposition of Glenn Vavoso (with accompanying exhibits)
- May 24th, 2021, Deposition of Edward W. Harrich (with accompanying exhibits)
- May 26th, 2021, Deposition of Katie Scoville (with accompanying exhibits)
- May 27th, 2021, Deposition of Bob DeSantis (with accompanying exhibits)
- May 27th, 2021, Deposition of Stacey Donovan (with accompanying exhibits)
- May 7th, 2021, Deposition of Myriam Curet (with accompanying exhibits)
- June 6th, 2021, Deposition of Chris Gibson (with accompanying exhibits)
- June 14th, 2021, Deposition of Joe Morris (with accompanying exhibits)
- June 4th, 2021, Deposition of Stan Hamilton (with accompanying exhibits)
- November 8th, 2022, 30(b)(6) Deposition of Grant Duque (with accompanying exhibits)
- November 8th, 2022, 30(b)(1) Deposition of Grant Duque (with accompanying exhibits)
- November 1st, 2022, 30(b)(6) Deposition of Greg Posdal (with accompanying exhibits)
- November 1st, 2022, 30(b)(1) Deposition of Greg Posdal (with accompanying exhibits)
- October 27th, 2022, 30(b)(6) Deposition of Keith Robert Johnson (with accompanying exhibits)
- October 27th, 2022, 30(b)(1) Deposition of Keith Robert Johnson (with accompanying exhibits)
- November 4th, 2022, Deposition of Sharathchandra “Shark” Somayaji (with accompanying exhibits)
- Expert Report of Dr. Joshua Sharlin dated July 26, 2021 Rebotix
- Expert Report of Dr. Robert Howe dated July 26, 2021 Rebotix
- Expert Report of Dr. Kim Parnell dated Aug 30, 2021 Rebotix
- Expert Report of Dr. Robert Howe dated Dec 02, 2022 SIS
- Expert Report of Dr. Amandeep Mahal dated Dec 01, 2022
- Expert Report of Kurt Humphrey dated Dec 02, 2022
- Rebotix's Responses and Objections to Intuitive's Second Set of Interrogatories
- Rebotix's Supplemental Responses and Objections to Intuitive's First Set of Interrogatories
- US Patent No. 5,797,900
- US Patent No. 6,991,627
- 1906 Pure Food and Drugs Act
- 2018 FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices
- 21 CFR § 803
- 21 CFR § 807.3
- 21 CFR § 807.81
- 21 CFR § 820
- 21 CFR § 820.198

- 21 CFR § 830
- BB000011
- BB000070
- BB000072
- BB000082
- BB000161
- BB000163
- BB000176
- BB000180
- BB000204
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- SIS146975
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- SIS000167
- SIS071311
- SIS045163
- Exhibit 238 of Deposition of Intuitive 30b(6) Designee Grant Duque Nov 08, 2022
- Exhibit 264 of Deposition of Intuitive 30b(6) Designee Grant Duque Nov 08, 2022
- Exhibit 201 of Deposition of SHARATHCHANDRA "SHARK" SOMAYAJI Nov 04, 2022